

CCSP CONCEPT/ANCILLARY STUDY REGISTRY Cardiac/Pulmonary/Renal Working Group										
WG update: May 23, 2022				Working Group Co-Chairs: Greg Armstrong & John Lynn Jefferies						
Principal Investigator/ Senior Mentor	Concept Title	Co-Investigators	Statistician/ Analyst	Objective	Eligibility Criteria	Date CPC Investigator Review/ Type	BIMS#/ SJLIFE#	Abstract	Date of Data Freeze	Analysis/ Manuscript Progress
Akbilgic/ Mulrooney	Machine Learning in Early Identification of Children at High Risk for Late-Onset Chemotherapy Induced Cardiotoxicity and Cardiomyopathy	Gunturkun Davis Karabayir Hudson Robison Ness Lucas Srivastava Armstrong Jefferies Soliman Howell		Early identification of childhood cancer survivors at high risk for cardiomyopathy.	Childhood cancer survivors with at least two ECHO screening following end of treatment and at least one ECG screening prior to last ECHO screening.	4/22/19		ASCO 2020 Poster	4/22/19	Published JCO CCI 2021 Analysis of Echo data to begin
Akbilgic/ Hudson	Machine Learning in Early Identification of Children at High Risk for Late-Onset Chemotherapy Induced Cardiotoxicity and Cardiomyopathy	Gunturkun Davis Hudson Srivastava Jefferies		Validation of ECG for early detection of cardiomyopathy, Targeting R01 response to RFA-CA-20-027.	Childhood cancer survivors with at least two ECHO screening following end of treatment and at least one ECG screening prior to last ECHO screening.	-			4/22/19	R01 Funded
Armstrong	The Etiology of Pulmonary Hypertension in SJLIFE Participants	Ness Joshi Robison Hudson Lenihan (Vanderbilt)	Srivastava	Right heart catheterization to determine the etiology of pulmonary HTN	SJLIFE participants exposed to chest RT and/or anthracycline and TR jet>2.8 and 6 min walk <600m	Opened June 2014			n/a	Pediatr Blood Cancer. 2017 Aug 26. Epub ahead of print
Armstrong	Retrospective Cardiac Assessment of Anthracycline and RT-exposed patients by MRI and Echocardiogram (ASCO CDA)	Ness Robison Green Hudson Joshi Arevalo Plana Flamm	Zhang Srivastava	To compare prevalence of cardiac outcomes measured by MRI, 3D and 2D echocardiogram	SJLIFE participants on HPP 1-5 who completed MRI and echo	12/13/2010 HPP/Grant Manuscript in preparation	2010CA04	JCO 2012 30:2876-84		J Clin Oncol. 2012;30(23): 2876-84
Armstrong	Longitudinal Cardiotoxicity in Adult Survivors of Childhood Cancer CARTOXII	Robison Hudson Green Ness Plana	Srivastava	Longitudinal follow up of CARTOX population (Aim 1) and strain evaluation (Aim 2)	Aim 1: Cartox population Aim 2: RT and Anthracycline exposed SJLIFE	NIH R01	2011CA03	ASCO 2018 Poster presentation JCO 36, 2018 (suppl; abstr 10565)	June 2016	1) <u>Exercise Intolerance:</u> Ness, JCO 2019 2) <u>QOL:</u> Hayek JAMA Onc 2020 3) <u>Family History:</u> CEBP 2021 4) <u>Biomarker:</u> Cancer 2021 5) <u>Autonomic Dysfunction:</u> Groarke, draft

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Armstrong	Comprehensive Assessment of Cardiac Function: Systolic, Diastolic and Myocardial Strain	Joshi Fowler Mulrooney Zhang Srivastava Santucci Hudson Green Ness Krasin Krull Robison Marwick Plana	Zhang	<ul style="list-style-type: none"> - To provide a comprehensive description of systolic and diastolic cardiac function, as well as myocardial strain (both longitudinal and circumferential strain), in a population of aging adult survivors of childhood cancer who received cardiotoxic therapy - To identify associations between echocardiographic cardiac function (systolic, diastolic, strain) and cardiopulmonary exercise performance measured using the six-minute walk test - To identify associations between myocardial strain and quality of life on the SF-36 	SJLIFE participants as of the April 2013 freeze (3031 exposed, 1828 participated and completed echocardiography), who received screening echocardiography secondary to exposure to anthracycline chemotherapy or chest-directed RT	11/25/2013	2013CA02	JCO 2014 32:664S	June 2014	J Am Coll Cardiol. 2015;65(23):2511-22
Armstrong	Effect of Heart Failure Risk Factors on Myocardial Dysfunction in Adult Survivors of Childhood Cancer	Marwick Plana Joshi Mulrooney Zhang Srivastava Hudson Ehrhardt Ness Robison Armstrong		To determine whether there is a significant association between conventional heart failure risk factors (listed below) and changes in objective measures of myocardial function (as measured by multiple echocardiographic parameters) and functional capacity (measured by 6MW) in adult survivors of childhood cancer who received cardiotoxic therapy	SJLIFE participants as of the April 2013 freeze (3031 exposed, 1828 participated and completed echocardiography), who received screening echocardiography secondary to exposure to anthracycline chemotherapy or chest-directed RT	10/05/2015	2015CA03		June 2015	JACC Cardiovasc Imaging. 2018 Aug;11(8):1202-1203
Armstrong/ Green	The Etiology of Pulmonary Hypertension in SJLIFE Participants	Ness Joshi Stokes Armstrong Robison Hudson	Zhu Srivastava	To study the epidemiology of pulmonary HTN; To determine which factors contribute independently to an increased risk for pulmonary HTN	SJLIFE participant exposed to chest RT and/or anthracycline	08/04/2009 Paper	3988 2009CA01	SIOP 2010	October 2009	J Clin Oncol 2013;31(6):774-81

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Bhatt	Whole Genome Sequencing Study to Identify Genetic Factors Associated with Coronary Artery Disease in Childhood Cancer Survivors: A Report from St. Jude Lifetime Cohort Study	Sapkota Yasui Mulrooney Jefferies Armstrong Wilson Robison Hudson		To identify genetic variants associated with coronary artery disease (myocardial infarction CTCAE grade 3 and 4) in childhood cancer survivors who are enrolled in the SJLIFE study	- Survivors of childhood cancer enrolled in SJLIFE of European ancestry - Completed on-site medical evaluations - Provided DNA samples for WGS	08/20/2018				Looking for replication cohort. Re-running analysis with updated number of MIs from most recent freeze and exploring other potential replication sources.

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Bhatt	: Longitudinal Changes in Pulmonary Function after Treatment for Childhood Cancer	Ness Gajjar Krasin Merchant McCarville Davidoff Srinivasan Stokes Srivastava Mulrooney Armstrong Hudson Robison Green		<p>Aim 1a: To study the longitudinal changes in pulmonary function measured by PFTs among survivors of childhood cancer enrolled in SJLIFE who have undergone at least two separate PFT assessments after completion of therapy</p> <p>Aim 1b: To identify factors associated with an increased risk of decline in pulmonary function measured by PFTs in this population</p> <p>Aim 2a: To study the relationship of radiation dose/ volume at low doses (V5, V10, V15, V20) with late pulmonary dysfunction measured by PFTs among childhood cancer survivors enrolled in SJLIFE who underwent at least one PFT assessment after completion of therapy</p> <p>Aim 2b: To study the association between pulmonary dysfunction identified by PFTs and self-reported symptoms and quality of life in this population</p> <p>Aim 2c: To study the association between pulmonary dysfunction identified by PFTs and functional assessment performed during SJLIFE campus visit in this population</p>	<p>Aim 1 will include childhood cancer survivors in SJLIFE, who are ≥ 18 years of age at their initial evaluation and have at least had two separate PFT assessments after completion of therapy during their comprehensive evaluation on the SJCRH campus regardless of their exposure to pulmonary toxic therapy (n=1279 according to the most recent data freeze).</p> <p>- Aim 2 will include all patients in the SJLIFE population who have at least had one comprehensive risk-based evaluation on the SJCRH campus including PFTs (n=3631 according to the most recent data freeze).</p>					

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Dixon	Abnormal Glucose and Insulin Homeostasis and Impact on Cardiac Function	Stephanie Dixon Carmen Wilson Kiri Ness John Jeffries Melissa Hudson Les Robison Wassim Chemaïtilly Greg Armstrong		Determine the prevalence of diabetes (defined as Hgb A1c $\geq 6.5\%$ or FPG ≥ 126 mg/dl) and prediabetes (defined as Hgb A1c 5.7-6.4% or FPG 100-125 mg/dl) in survivors of childhood cancer utilizing the St Jude Lifetime Cohort compared to the prevalence in both community controls and an age-, gender-, ethnicity- and BMI category matched US population from the NHANES dataset.	- Enrolled in the St. Jude Lifetime Cohort who completed an on campus visit and have at least one fasting plasma glucose and/or hemoglobin A1c measurement as of the most recent SJLIFE data freeze.	01/14/2019		ASCO 2020 Poster		Analysis Underway R21 PreDM Resubmission Not funded. Abstract submit to SIOP 2022

Dixon	Categorization of Clinical Heart Failure in SJLIFE	Yaranov Rhea Ehrhardt Mulrooney Goldberg Nagueh Jefferies Ness Robison Hudson Armstrong		<p>Aim 1. Describe the prevalence of heart failure in St. Jude Life participants and controls overall and by stage (none, A, B, C, D). Among survivors with heart failure (stage C and D) we will further classify by systolic function (HFrEF, HFpEF, HFmrEF, HFimpEF) and New York Heart Association classification (I, II, III, IV).</p> <p>Aim 2. Compare the prevalence of heart failure by the above categorizations to CTCAE grading for LVSD/cardiomyopathy</p> <p>Aim 3. Evaluate the risk factors for heart failure (Y/N) and by systolic function (HFpEF or ever reduced EF: HFrEF, HFmrEF, HFimpEF) using treatment and traditional variables demographic variables and cardiovascular risk factors.</p> <p>Aim 4. Evaluate the risk of death by heart failure group (none, A, B, C, D), NYHA class, and HFrEF/HFpEF categorization at first recorded assessment and as a time varying covariate. Reporting the median follow-up for each group. Compare this to the risk of death by CTCAE grade for LVSD.</p>	- Enrolled in the St. Jude Lifetime Cohort who completed an on campus visit at age ≥ 18 years and have at least one visit with: echocardiogram, survey completion at the same visit timepoint (+/- 3 months of core assessment) and either 6MWD or CPET. A subpopulation of survivors who also have at least one visit with NT-proBNP and both 6-minute walk test and CPET with maxVO2 will also be assessed separately.					
Ehrhardt/ Armstrong	Refining Cardiomyopathy Risk Prediction	Goldberg Dixon Ness	Yasui	Develop simple, standard, and advanced prediction models incorporating increasing levels	- All SJLIFE with echos and follow up	08/16/2021				Analysis under way; Abstract

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		Sapkota Yasui Srivastava Mulrooney Mazur Jefferies Robison Hudson		of discreet data utilizing proportional hazards models and a time-dependent receiver operating characteristic (ROC) curves to predict heart-failure, based on a training subset of SJLIFE that was selected by stratified random sampling.						submitted to ISLCCC Poster at ASCO 2022
Gibson	Blood Pressure Status in Adult Survivors of Childhood Cancer	Li Green Armstrong Mulrooney Srivastava Bhakta Ness Hudson Robison	Li Srivastava	Estimate the age-specific cumulative prevalence of hypertensive blood pressure, investigate participant and treatment factors associated with blood pressure status, and examine longitudinal blood pressure measurements	SJLIFE participants who completed at least one campus visit with blood pressure measurements	Paper		Oral presentation AACR Advances in Pediatric Cancer Research, 2015	June 2016	Cancer Epidemiol Biomarkers Prev. 2017 Dec;26(12):1705-1713.
Gibson	Cigarette Smoking, Pulmonary-Toxic Therapies and Pulmonary Function in Survivors of Childhood Cancer	Green Armstrong Mulrooney Hudson Robison		-To examine associations between smoking status or smoking history and measures of pulmonary function in survivors of childhood cancer, overall and stratified by receipt of pulmonary-toxic cancer therapies -investigate potential interactions between smoking status or smoking history and pulmonary-toxic therapies for associations with pulmonary function. -examine associations between smoking patterns and longitudinal changes in pulmonary function among survivors who have had multiple St. Jude Life visits that included pulmonary function testing	- Participants in SJLIFE who had pulmonary function testing results as of the most recent SJLIFE data freeze. - All St. Jude Life participants who were exposed to pulmonary toxic therapy were designated for pulmonary function testing during their initial SJLIFE on-campus visit.					Analysis Complete; Decided not to publish at this time

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Goldberg	Dyslipidemia and Association with Cardiovascular Disease in Survivors of Childhood Cancer	Rohatgi Ness Srivastava Dixon Mulrooney Erhardt Jefferies Towbin Robison Hudson Armstrong		Determine the prevalence of and risk factors for dyslipidemia and associations with cardiac disease.	All SJLIFE participants					Analysis Underway; manuscript drafted
Goldberg	Cardiac MR and Biomarkers in Children During Hematopoietic Cell Transplantation (HCT)	Towbin Armstrong Triplett Johnson, J Srivastava Sen	Srivastava	Determine detection feasibility and generate prospective preliminary evidence for the prevalence of cardiotoxicity (both myocardial injury and systolic dysfunction) via longitudinal, advanced myocardial imaging during the first year of pediatric HCT. Identify preliminary evidence for the prevalence of clinical and serum biomarkers of inflammation and cardiac injury during HCT therapy.	Patients undergoing active HCT					K23 Submission October 2021 Not scored
Green	Resistance and Aerobic Exercise for Subclinical Anthracycline Cardiomyopathy (CARHAB)	Ness Krull Kaste Plana Folse Joshi Armstrong Hudson	Srivastava	To evaluate feasibility of 12-week exercise intervention on cardiac function of survivors of childhood cancer treated with anthracyclines and known to have cardiomyopathy	Treatment with doxorubicin/ daunorubicin; Ejection fraction of < 55% on no medications; Does not meet CDC recs for exercise	08/05/2008 09/13/2011 Ancillary Study	3916 2008CA01	Poster presentation at Experimental Biology, 2013	April 2013	Pediatr Blood Cancer 2014;61:942–945
Green	Pulmonary Function after Spinal Irradiation	Ness Gajjar Krasin Merchant Lukose Srinivasan Stokes Smith Srivastava Armstrong Hudson Robison	Srivastava	To estimate the prevalence of abnormal pulmonary function and identify factors associated with an increased risk of abnormal pulmonary function in survivors of ALL or CNS malignancies whose treatment included spinal irradiation	Patients who have undergone evaluation of pulmonary function one or more times after the completion of radiation therapy that included spinal irradiation for the treatment of ALL, medulloblastoma or ependymoma in the SJLIFE population	06/13/2011 Paper	4434 2011CA02			On Hold: pending accrual of additional ALL survivors.

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Green	Pulmonary Function After Surgical Treatment of Pulmonary Metastases from Osteosarcoma	Denbo Ness Smith Navid Srinivasan Stokes Hudson Davidoff Rao Neel Robison	Zhu Srivastava	To estimate the frequency of impairment of pulmonary function after thoracotomy for resection of metastases from osteosarcoma and determine which clinical data may help predict impairment of pulmonary function	≤ 18 years at diagnosis s/p surgical resection of osteosarcoma pulmonary metastasis	Paper	4235 2011CA04	Poster presentation Society of Surgical Oncology 2013	April 2013	J Am Coll Surg. 2014;219(2):265-71
Green	Pulmonary Function after Treatment for Childhood Cancer	Ness Gajjar Krasin Merchant McCarville Metzger Navid Davidoff Denbo Rao Srinivasan Stokes Smith Srivastava Mulrooney Armstrong Hudson Robison	Srivastava	Estimate the prevalence of abnormal pulmonary function in survivors of childhood cancer whose treatment included thoracic irradiation, thoracic surgery and/or exposure to chemotherapeutic agents that produce pulmonary damage	SJLIFE participants who have received pulmonary toxic therapy as defined in the COG Guidelines and those who underwent chest wall surgery (rib resection, thoracotomy, etc.)	03/04/2013 03/04/2013-2	2013CA01	Poster presentation ASCO 2015	April 2013	Ann Am Thorac Soc. 2016 13(9):1575-85.
Green	Renal Function after Treatment for Childhood Cancer	Zhu Srivastava Mulrooney Bissler De Los Santos Ness Ojha Navid Spunt Davidoff Robison Hudson	Zhu	To assess the prevalence of impaired renal function in adult survivors of childhood cancer who are ten or more years post-diagnosis and evaluate the associations between treatment exposures and nephrectomy, and impaired renal function	Patients who completed SJLIFE assessment and received nephrotoxic therapy.	11/25/2013 paper	2013EB02 BIMS 4908	Poster presentation ASCO 2016	10/2013	J Am Soc Nephrol. 2021 Mar 2;32(4):983-93.

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Green	Longitudinal Evaluation of Kidney Function	Wang Srivastava Zaidi Krasin Ness Ongul Mulrooney Ehrhardt Dixon Davidoff Robison Hudson		Determine longitudinal course of GFR.	Age >18 years at initial SJLIFE evaluation	7/2021				Analysis in Queue
Groarke/Ness	Feasibility and Accuracy of Remote Evaluation of Resting Heart Rate and Heart Rate Variability in Survivors of Hodgkin Lymphoma Treated with Chest Radiation (PILOT STUDY-SURVIVOR)	Armstrong Gibson Krull Krasin Mulrooney Hudson Robison Ness		To determine the feasibility and accuracy of remote evaluation of resting heart rate and HRV using the commercially available WHOOP® wrist monitor, compared to in-office measurements using AtCor Medical SphygmoCor HRV Software	Enrolled in the SJLIFE study. Survivor of childhood Hodgkin lymphoma. Exposure to ≥ 20 Gy chest radiation Is 18 years of age and older. No evidence of cancer recurrence. Non-smoker at time of study participation. Willingness to avoid caffeine for 3-4 hours and alcohol for 8 hours prior to testing. No history of allergic reactions to ECG electrodes.	10/22/2018	2018CA02			Manuscript Draft R01 submission: October 20221: WEAR IT; Not scored. Consider resubmission

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Im	Genetic Risk Prediction Profiles for Pulmonary Dysfunction Outcomes among Childhood Cancer Survivors	Mulrooney Green Stokes Ness Wilson Sapkota Hudson Robison Yasui		<ul style="list-style-type: none"> - Conduct a GWA study with whole genome sequencing (WGS) data to identify common single nucleotide variants (SNVs) and insertions and/or deletions (indels) associated with select pulmonary dysfunction outcomes and related PFT measures among SJLIFE childhood cancer survivors - Conduct a GWA study with WGS data to identify common SNVs and indels that modify treatment effects on select pulmonary dysfunction outcomes and related PFT measures among SJLIFE childhood cancer survivors - Conduct a whole-genome association study to identify rare SNVs and indels associated with select pulmonary dysfunction outcomes and related PFT measures among childhood cancer survivors - Assess the extent to which specific sets of genetic predictors improve the discriminatory performance of standard clinical prediction models for pulmonary dysfunction outcomes among childhood cancer survivors 	Participants meeting all of the following criteria are eligible for inclusion in this analysis: <ul style="list-style-type: none"> •Survivors of childhood cancer with ≥5 years survival since primary diagnosis •Provided a DNA sample for sequencing •European ancestry (determined by principal components analysis of genotype data) •Did not receive allogeneic bone marrow transplantation •No excess per-sample heterozygosity or cryptic relatedness (genotype data) •Sex concordance (genotype data) •≤5% per sample genotype data missingness 	Oct. 15, 2018		Submitted to ASHG 2020	Dec. 31, 2018	Manuscript submitted
Interiano	Scoliosis after Thoracotomy in the SJ Life Cohort	Davidoff Hudson Ness Rao Pappo Green Neel Fernandez-Pineda Mulrooney Armstrong Kaste Robison		<ul style="list-style-type: none"> - To compare the prevalence of scoliosis among survivors of childhood sarcoma who did and did not have thoracotomy or chest wall resection for management of their disease - To evaluate the impact of scoliosis on pulmonary and physical function among sarcoma survivors 	SJLIFE participants diagnosed with childhood sarcoma	02/09/2015	2015CA01	Poster presentation American Pediatric Surgical Society 2016	June 2015	J Cancer Surviv. 2017 Oct;11(5):553-561

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Howell/ Mulrooney/Yasui	Personalized Risk Based on Cardiac Substructure RT Dose Prediction to Reduce Cardiovascular Disease	Shrestha Yasui Armstrong Jefferies Chow Oeffinger Hudson Robison Bates Constine Pinnix Paulino Ehrhardt Armenian	Yasui	<ul style="list-style-type: none"> - Develop in SJLIFE and validate in CCSS risk prediction models for cardiomyopathy, CAD, valve disease incorporating cardiac Rt substructure doses - Integrate CV risk prediction models into a commercial RT treatment planning system and establish their use for contemporary patients 	Survivors receiving chest RT	10/18/2021				R01 resubmission; R01 Funded Existing Data Analysis in Queue
Jefferies	Cardiac Remodeling in Aging Survivors of Childhood Cancer	Hudson Robison Green Mulrooney Plana Towbin Goldberg Martinez Ness Srivastava Armstrong	Srivastava	<ul style="list-style-type: none"> - To evaluate the prevalence of pathologic LV remodeling: 1) Primary outcome: categorization into four groups based on changes in relative wall thickness (RWT) and LV mass indexed (LVMi) (Figure 1), and 2) Secondary Outcome: assessment of ten individual measures of remodeling, in survivors of childhood cancer overall, and stratified based on exposure to: anthracyclines alone, chest RT alone, both, or none. - To identify risk factors associated with pathologic LV remodeling including cumulative anthracycline and radiation dose exposures and time from initial exposure. - To identify longitudinal changes in pathologic LV remodeling as survivors age in those with multiple echocardiographic evaluations. - To assess for differences in the type and degree of pathologic remodeling based on gender. 	Enrolled in SJLIFE and completed an on campus visit including at least one transthoracic echocardiogram.	4/22/2019				Cancer. 2021 epub Aug 19th

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Lubas	Stress/Psychological Distress and Cardiac Late Effects in Adult Survivors of Childhood Cancer	Armstrong Ness Jeffries Srivastava Krull Robison Hudson Brinkman	Srivastava	<ul style="list-style-type: none"> - To examine the unadjusted and adjusted associations between measures of stress/distress and cardiac late effects among survivors of childhood cancer. Adjusted models will include demographic variables, treatment exposures, traditional cardiovascular risk factors, and lifestyle behaviors. - To investigate potential interactions between stress/distress, cardiovascular risk factors, and lifestyle behaviors for associations with adverse cardiac outcomes. Due to limited prior research on the influence of stress/distress and cardiovascular risks among adult survivors of childhood cancer, we plan to examine several interaction terms. - To examine longitudinal associations between measures of stress/distress and cardiac late effects among survivors of childhood cancer who have completed multiple SJLIFE questionnaires and campus visits. The potential for bidirectional relationships between stress/distress and adverse cardiac outcomes will be examined. 	Enrolled in SJLIFE; >18 years of age and completed a SJLIFE questionnaire and a campus visit.					Manuscript Published CEBP 2021
Martinez	Right Heart Failure in Adult Survivors of Childhood Cancer	Jefferies Mazur Beasley Goldberg Apsi Joshi Towbin Armstrong Green	Srivastava	<ul style="list-style-type: none"> - To assess prevalence of RV systolic dysfunction (RVSD) by echo (TAPSE, RV strain and S') from CARTOX population. - To determine the association of abnormal PFT and RVSD - To determine the association between RVSD and 	CARTOX population with concomitant echo and CPET					Waiting for TOMTEC software

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		Ness Hudson Robison Srivastava Jefferies		cardiopulmonary exercise testing (CPET) - To identify associations between RVSD and treatment exposures - To identify longitudinal changes in RV function						
Mazur/ Armstrong	LA Volume: Comparison of Single vs. Biplane method	Mazur Palmer Truong Fowler Shelton Joshi Ness Srivastava Robison Hudson Jefferies Armstrong	Truong	Comparison of single vs. biplane method	All SJLIFE with Echo eval	-				Manuscript rejected at Echocardiography New submission pending
Mazur/Joshi	Comprehensive Assessment of Ventricular Diastolic Dysfunction in Childhood Cancer Survivors	Mulrooney Srivastava Santucci Hudson Green Ness Krasin Krull Robison Marwick Plana Armstrong	Srivastava	- To describe the prevalence (ASE grades 1-3) and pattern (septal e', lateral e', LA volume, E/A, DT, Average E/e') of diastolic cardiac function, in a population of aging adult survivors of childhood cancer who received cardiotoxic therapy - To assess the influence of increasing doses of chest RT on diastolic dysfunction prevalence and pattern. - To assess the influence of hypertension and other traditional cardiovascular risk factors on diastolic function - To identify associations between echocardiographic cardiac systolic and diastolic dysfunction	SJLIFE participants who received screening echocardiography secondary to exposure to anthracycline chemotherapy or chest-directed RT	03/09/2015	2015CA02		April 2013	Manuscript Drafted; Undergoing additional analysis
Metzger	Peripartum Cardiomyopathy in Childhood Cancer Survivors	Hines-Thomas Hudson Mulrooney		Describe the incidence of peripartum cardiomyopathy in female patients previously treated for pediatric childhood cancer and evaluate the risk	Female cancer survivors, ≥ 5 year from diagnosis, age > 13 years at time of study, be a St Jude alumni, in ACT clinic, or part of SJLIFE study with previous pregnancy	10/01/2012 Paper	2012CA04			J Cancer Surviv. 2016;10(1):113-21

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Mulrooney	Arrhythmias and Conduction Disorders in Survivors of Childhood Cancers	Mulrooney Armstrong Joshi Hudson Krasin Srivastava Robison Zhang Soliman Li Ness	Srivastava	To determine the frequency of arrhythmias and conduction disorders identified on ECGs among adult survivors of childhood cancer	- Were treated for primary cancer diagnosis at St. Jude - > 10 years from diagnosis - > 18 years of age at evaluation - Have completed a comprehensive risk-based health evaluation on the SJCRH campus	03/26/2012 Paper	BIMS 4601 2012CA01	Poster presentation SIOP 2014 Oral presentation Int'l Late Effects Meeting Alexandria, VA 2015	June 2015	Am Heart J. 2017 Jul;189:19-27
Mulrooney	Vascular Assessment of Adult Survivors of Childhood Cancer	Srivastava Ehrhardt Hebbel Duprez Joshi Ness Green Santucci Smith Robison Hudson	Huang	Evaluate biomarkers of vascular injury (inflammation, hemostasis, endothelial activation) and assess vascular function among childhood cancer survivors compared to age/gender-matched controls	- Treated for a primary diagnosis of Hodgkin lymphoma with radiation therapy or a primary diagnosis of sarcoma treated with chemotherapy only, no radiation therapy, - Younger than 21 years old at diagnosis - No history of cardio- or peripheral vascular disease	09/17/2012 Study	2012CA02 BIMS 4561	ASCO 2017 Poster presentation J Clin Oncol 35, 2017 (suppl; abstr 10564) Oral presentation Int'l Late Effects Meeting Atlanta, GA 2017	June 2016	Manuscript Draft

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Principal Investigator/ Senior Mentor	Concept Title	Co-Investigators	Statistician/ Analyst	Objective	Eligibility Criteria	Date CPC Investigator Review/ Type	BIMS#/ SJLIFE#	Abstract	Date of Data Freeze	Analysis/ Manuscript Progress
Mulrooney	Cardiac Outcomes in Aging Survivors of Childhood Cancer	Armstrong Joshi Srivastava Ness Green Santucci Smith Krasin Robison Hudson	Huang	<ul style="list-style-type: none"> - To describe the prevalence of sub-clinical and clinical cardiac outcomes in the SJLIFE cohort prior to and following risk-based screening - To assess the effects of the primary cancer, treatment modalities, and cardiovascular risk factors on the risk of developing late adverse cardiac outcomes 	<ul style="list-style-type: none"> - Were treated for primary cancer diagnosis at St. Jude - ≥ 10 years from diagnosis - ≥ 18 years of age at evaluation - Have completed a comprehensive risk-based health evaluation on the SJCRH campus. Subjects available N=2240 (per SJLIFE data freeze April 30, 2012; will update after October 31, 2012 data freeze) 	10/15/2012 Paper	2012CA03 BIMS 4716	Poster discussion ASCO 2014 (JCO 2014 32:655S)	April 2013	Ann Intern Med. 2016;164(2):93-101
Mulrooney	Coronary Artery Disease Detected by Coronary Computed Tomographic Angiography in Adult Survivors of Childhood Hodgkin Lymphoma	Nunnery Donovan Ness Smith Srivastava Robison Hudson Metzger Armstrong Durand Flamm	Srivastava	To describe subclinical coronary artery disease detected by coronary CT angiography (CCTA) in a cohort of high-risk, asymptomatic, long-term survivors of HL exposed to chest radiotherapy alone (≥ 30 Gy) or chest radiotherapy (<30 Gy) plus anthracycline chemotherapy	<ul style="list-style-type: none"> - Survivor of Hodgkin lymphoma enrolled in the SJLIFE cohort study <ul style="list-style-type: none"> a. Participants in HPP4 <ul style="list-style-type: none"> i. Greater than 15 years from initial diagnosis ii. Currently less than 55 years of age iii. Received mediastinal or chest irradiation ≥ 30 Gy b. Participants in HPP5 <ul style="list-style-type: none"> i. Greater than 15 years from initial diagnosis ii. Currently less than 55 years of age iii. Received mediastinal or chest irradiation iv. Received anthracycline chemotherapy 	HPP 4 HPP 5				Cancer. 2014; 120(22):3536-44

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Mulrooney	Left Ventricular Non-Compaction			<p>Specific Aim 1: Estimate the prevalence of and evaluate treatment and demographic related risk factors associated with LVNC among survivors of childhood cancer</p> <p>Specific Aim 2: Examine associations between LVNC and cardiac morbidity (cardiomyopathy, coronary artery disease, rhythm abnormalities) among survivors of childhood cancer</p> <p>Exploratory Aim: Assess correlations across LVNC diagnostic criteria (echocardiographic and CMR) in adult survivors of childhood cancer.</p>	-					Resubmitted as R01 in October 2021 Not funded. Plan for PRCRP Idea Award Application and R21 in fall.
Ness	CARTOX III/Home Heart Health	Robison Hudson Brinkman Srivastava Armstrong Jefferies	Srivastava	To determine the efficacy of an individually tailored, home-delivered aerobic, and strengthening intervention to improve exercise capacity in survivors of childhood cancer with exercise intolerance (peak oxygen uptake (peak VO2) <85% of age and sex predicted).	<p>≥18 years of age</p> <ul style="list-style-type: none"> • SJLIFE participant • peak VO2 <85% predicted • understand directions for use of ZOOM (free video communication application that allows screen sharing (so the exercise specialist can see heart rate in real time https://zoom.us/) and sessions can be recorded) on the study provided iPad and heart rate monitor • clearance for participation in exercise by a study physician • internet access (91% of cohort members have access) 					<p>FUNDED!!</p> <p>Enrolling</p>

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Ness	Autonomic Function in Survivors (CCSS)	Armstrong Ehrhardt Brinkman Others?		Using mHealth technologies in a large and well-characterized cohort of childhood cancer survivors, understand the magnitude of increased risk of cardiac autonomic dysfunction by (a) comparing prevalence rates among survivors and siblings, and (b) determining the prevalence within specific subgroups of childhood cancer survivors defined by race, sex, primary cancer type and treatment exposures, and type and severity of chronic health conditions.						Submitted as R01 Fall 2021; not scored; considering resubmission
Nottage	Cardiovascular Risk Factors in Adult Survivors of Childhood Acute Lymphoblastic Leukemia	Hudson Ness Robison	Li Srivastava	To determine prevalence of metabolic syndrome and other cardiovascular risk factors among ALL survivors / compared to general population	Any ALL survivors who completed their SJLIFE evaluations as of 3/4/10 Blocks 1-32	11/19/2009 Manuscript in preparation 4/2013	BIMS 4306 2009CA02	SIOP 2010	October 2011	Br J Haematol 2014;165(3): 364-74
Scott	Association of Ideal Cardiovascular Health Score with Major Cardiovascular Events in Adult Survivors of Childhood Cancer	Ness Yasui Li, N Liu, Q Adams Robison Mulrooney Armstrong Hudson Jones		- To examine the association between iCVH score and composite incidence of any major (grade 3 to 5) CVD events among ASCC after adjusting for key clinical covariates. - To examine the validity of self-reported iCVH score components.		3/19/2018	2018CA01			Analysis no longer progress.
Smith/ Ness	Dietary Intake and Metabolic Syndrome in Adult Survivors of Childhood Cancer	Nottage Hudson Lancot Green Gurney Nolan Laver Robison Ness	Li	- To characterize dietary intake based on adherence to dietary strategies associated with lower risk for MetS and CVD - To evaluate the associations between dietary intake and MetS	Survivor of ALL who completed Food Frequency and Health Habits	12/06/2010	BIMS 4306 2010CA03	ASCO 2012 Williamsburg 2012	April 2003	Cancer 2014;120(17):2742-50

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Wilson	Longitudinal changes in Cardiopulmonary fitness and adverse health outcomes in survivors of childhood cancer	Wogksch Srivastava Partin Krull Armstrong Jefferies Mulrooney Hudson Robison Ness		<p>To determine if the age-associated decline in exercise capacity (VO2 max, 6-minute walk) is greater in survivors of childhood cancer when compared with normative data.</p> <p>To identify demographic, diagnosis and treatment-related predictors of decline in exercise capacity among survivors.</p> <p>To assess the association between exercise capacity and development of new adverse health outcomes (tentative list of adverse outcomes are cardiac and pulmonary CTCAE Grade 3-4 conditions, increased risk of frailty, and reduced cognition.</p>	SJLIFE participants (18 years and older) with ≥ 2 assessments for peakVO2 <u>OR</u> ≥ 2 assessments for 6MW through to the most recent data freeze					
Wogksch	Validity of the chest wall expansion measurement among adult survivors of childhood cancer	Wolcott Armstrong Mulrooney Ehrhardt Green, D Jefferies Srivastava Krasin Davidoff Sodhi Kadaria Robison Hudson Ness	Srivastava	- Assess the ability of chest wall expansion to accurately predict restrictive pulmonary defects in comparison to plethysmography (TLC),	Adult >18, with functional assessment in HP lab with PFTs	1/30/2021				Draft of manuscript with Kiri

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Brooke Chemaitilly Yasui	Characterizing Anti-Müllerian Hormone (AMH) Levels in Female Survivors of Childhood Cancer with the High-Risk Haplotype for Premature Menopause (PM): A report from the St. Jude Lifetime Cohort Study.	Sapkota van der Kooi van Dulmen - den Broeder Moon Krasin Uitterlinden Green Howell Li Wilson van den Heuvel-Eibrink Sklar Hudson Robison		To compare the levels of AMH in participants who have two copies of the high-risk haplotype for PM with those who do not have two copies, including stratification by treatment exposure in individuals with or without clinically diagnosed PM.	SJLIFE participants included in the original high-risk haplotype study	07/30/2018				On hold for more cases
Brooke Clark Yuan Yasui	Predicting Acute Ovarian Insufficiency: Report from the CCSS	Vu Lu Mostoufi-Moab Sklar Howell Gibson Hudson Oeffinger Armstrong Nathan		Validation of risk prediction model in SJLIFE	Female SJLIFE participants with / without AOF	Not reviewed (replication request)				Oncol. 2020 Mar;21(3):436-445.
Chemaitilly	Anterior Hypopituitarism in Adult Survivors of Childhood Cancers Treated with Cranial Radiotherapy	Li Huang Ness Clark Green Barnes Armstrong Krasin Srivastava Pui Merchant Gajjar Hudson Robison Sklar	Li	To estimate the prevalence of deficiencies of GH, LH/FSH, TSH, and ACTH in SJLife participants treated with cranial radiotherapy (CRT) and to identify associated risk factors for deficiencies, and to assess the impact of untreated deficiencies.	SJLife participants treated with CRT	09/20/2012 Paper		ESPE-PES Joint Meeting 2013	4/2012	J Clin Oncol. 2015;33(5):492-500

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Chemaitilly	Central Precocious Puberty as a Consequence of Central Nervous System Tumors and Cranial Radiotherapy: Presentation, Progression and Long-term Growth, Metabolic and Gonadal Outcomes	Chemaitilly Merchant Li Barnes Armstrong Ness Pui Kun Hudson Robison Sklar Gajjar	Li	To describe the presentation of CPP, progression and long-term outcomes in terms of final height, obesity, and gonadal function.	Patients with CPP followed in endocrinology since 1-1-2002 including 20 SJLIFE participants	01/27/2014 Paper (via SJLIFE planning meeting discussion)		ESLCCC meeting 2014		Clin Endocrinol (Oxf). 2016;84(3):361-71
Chemaitilly	Primary Ovarian Insufficiency in Childhood Cancer Survivors: A report from the SJLIFE Cohort	Li Ness Green Krasin Farr Srivastava Pui Metzger Fernandez-Pineda Hudson Robison Sklar Yasui	Li	To describe the prevalence of primary ovarian failure and premature menopause and to determine which cancer treatment factors, patient characteristics, lifestyle variables independently increase the risk of each of these conditions among SJLife survivors and evaluate genetic associations (GWAS)	Female survivors in SJLIFE	09/20/2012 Paper		ESPE 9-2016	4/2012	J Clin Endocrinol Metab. 2017 Mar 24. doi: 10.1210/jc.2016-3723
Chemaitilly	Leydig Cell Dysfunction in Survivors of Childhood Cancer- A Report from the St. Jude Lifetime Cohort Study	Liu, Q. Klosky Wilson Ness Krasin Navid Metzger Armstrong Srivastava Amar Kun Pui Hudson Robison Sklar Green	Liu, Q	- To describe the prevalence of Leydig cell failure (LCF) and compensated LCF in survivors among the SJLIFE cohort and the proportion of new diagnoses and to study associations with various factors. - To assess the prevalence of psychosexual and physical symptoms in LCF and compensated LCF and to study the effects of LCF and compensated LCF	- Male - Completed SJLIFE campus visit and physical performance assessment - 18 years of age and above at the time of study	08/18/2014	2014ER02	ENDO-2019		J Clin Oncol. 2019 Nov 10;37(32):3018-3031.

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Chemaitilly Krull Ness	Thyroid Function Parameters and Adverse Neurocognitive, Quality of Life, Physical Fitness and Thyroid Neoplasia Outcomes in Childhood Cancer Survivors	Armstrong Lam Wilson Brinkman Krasin Metzger Bishop Sabin Triplett Pui Gajjar Srivastava Green Robison Hudson Sklar	Li Huang	- To describe the prevalence and predictors of primary hypothyroidism (Phypo) and primary hyperthyroidism (Phyper) including subclinical forms in SJLIFE - To examine the contribution of Phypo and Phyper and study associations between abnormal thyroid function labs and neurocognitive problems, frailty phenotype, cardiovascular risk factors, impaired quality of life, depression, social attainment and secondary thyroid cancer	Inclusion criteria: SJLIFE participants who have completed a campus visit including neuropsychology evaluations and assessments in the human performance lab	4/24/2017	2017ER02		2016	Cancer. 2022 13Feb; 128(3):606-614. doi: 10.1002/cnrc.33969.
Delaney Yasui	Risk Prediction for Premature Ovarian Insufficiency in Childhood Cancer Survivors	Yuan, Yan Lu, Z (Michael) Mostoufi-Moab Nathan Chow Howell Armstrong Robison Hudson	Baedke	- Validation of risk prediction model for POI in SJLIFE	Female SJLIFE participants with / without POI	4/12/2021 (brief presentation of replication study; not full concept proposal)		Submitted to ISLCCC, July, 2022		Analysis complete.
Dixon Armstrong	PREDM. A pilot intervention trial to prevent diabetes in prediabetic adult survivors of childhood cancer.	Dixon Ness Armstrong Hudson Freedman Erhardt Brinkman Mulrooney Folse Salehabadi Srivastava Merchant Robison		- To establish the feasibility and safety of a 24-week combined metformin + digitally delivered lifestyle intervention among adult survivors with prediabetes - To examine preliminary efficacy of the combined intervention on glycemic control and insulin resistance. - - To examine preliminary efficacy on anthropometric measures, physical activity, frailty, BP, lipids and HRQOL	Adult survivors age 18- <45 with prediabetes and a cancer treatment related risk factor for diabetes development	n/a Grants: Conquer Cancer Career Development Award (Dixon, 2021-2024; St. Baldrick's Foundation Fellow Award (Dixon, through 2022)				

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Fernandez-Pineda/ Chemaitilly	Ovarian Function after Ovarian Transposition in Long-term Survivors of Hodgkin Lymphoma: A Report from the St. Jude Lifetime Cohort Study.	Davidoff Rao Wilson Srivastava Klosky Metzger Krasin Ness Pui Robison Hudson Green Sklar	Lu	To study the effect of fertility preservation surgery on long-term ovarian outcomes in HL survivors treated with pelvic RT	SJLIFE participants with a history of HL and who were exposed to pelvic RT	CPC review completed 06/27/2016	2016ER01	Oral pres. SIOP 2017	6/30/2015	Pediatric Blood Cancer. 2018 May 11: e27232
Goodenough/ Ness* *and Inaba as co-PI on R01 submission	Designing and Implementing a Dietary Intervention to Remediate or Prevent Obesity During Childhood ALL Therapy	Mazzucca Srivastava Tillery Browne Carney Ringwald-Smith Roberts Okoth	TBD	-Evaluate perceptions of stakeholders on the acceptability for a dietary intervention to remediate or prevent obesity during childhood ALL therapy. -Accordingly design an intervention in a small group of families of children with ALL during cancer therapy based on aim 1 findings. -Conduct a pilot study of the modified dietary intervention in a representative group of families of children with ALL starting during induction therapy.	TBD	review completed 5/12/2021				R01 being resubmitted. LOI submitted (AICR) to fund pilot data/Aim 1
Gawade/Ness	Association of Bone Mineral Density, Renal Calcifications and Risk Factors for Their Development	Ness Kaste Srivastava Spunt Hudson Nottage Krasin Robison Sharma	Srivastava/ Li	To investigate the association between renal calcifications, BMD and risk factors	ALL survivors who completed QCT	03/28/2011 Paper	BIMS 4272			Cancer Surviv. 2012;6(4):388-97

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Goodenough	Muscle Health in Childhood Cancer Survivors: A Report from the St. Jude Lifetime Cohort Study	Wilson Chemaitilly Mirzaei Kaste Hudson Robison Ness	Mengqi Xing	Aim 1a. Determine the prevalence of reduced muscle health in childhood cancer survivors compared to community controls. Aim 1b. Evaluate the relationship between muscle mass, strength, and physical performance in childhood cancer survivors compared to community controls. Aim 2a. Identify host and cancer related treatment variables associated with muscle health in survivors. Aim 2b. Determine the impact of modifiable risk factors on decline in muscle health during survivorship. Aim 2c. Evaluate the impact of muscle health on risk for metabolic syndrome and mortality among survivors.	Participants enrolled in St. Jude Lifetime Cohort who were > 18years of age at completion of on campus visit, have both DXA and physical performance assessment data available, as of the most recent SJLIFE data freeze.	06/28/2021			4/2020	Analysis in progress
Goodenough/ Ness and Chemaitilly	Bone Mineral Density (BMD) deficit in Childhood Cancer Survivors: A Report from the St. Jude Lifetime Cohort Study	Nan Li Baedke Brinkman Delaney Wilson Inaba Clark Armstrong Mulrooney Barnes Srivastava Triplett Pui Hudson Robison Green Yasui Kaste	Li/Baedke	To describe the prevalence of BMD deficit, its risk factors and long-term consequences on health and quality of life	SJLIFE participants age \geq 18 years old	03/16/2020 Paper		2022 SJCRH Postdoc Symposium 2022 ASCO (submitted) 2022 ISLCCC (submitted)	2/2018	Analysis in progress

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Yu/ Green/Ness	Anti-Müllerian Hormone in Female Childhood Cancer Survivors in the St. Jude Lifetime Cohort Study	Delaney Bjornard Kutteh Meacham Brooke Merchant Pui Armstrong Wilson Yasui Chemaitilly Srivastava Ness Hudson Robison	Wang, M.	To investigate AMH as a marker of follicular reserve in childhood cancer survivors and assess correlations with demographic factors, treatment exposures and clinical outcomes including infertility symptoms and perceptions of infertility.	SJLIFE female participants who did not have oophorectomy (unilateral or bilateral) or central hypogonadism prior to assessment	05/18/20	BIMS 6122			Analysis in progress
Green	The Relationship between Semen Analysis Results and Treatment Exposures in SJLIFE Participants	Klosky Spunt Metzger Navid Robison Hudson	Zhu Srivastava	To evaluate the frequency of oligospermia (> 0/ml and < 20 million/ml), azoospermia (0/ml) and other semen abnormalities	SJLIFE participant who completed semen analysis	08/04/2009 Paper	BIMS 4027	SIOP 2011	4/2013	1-Inhibin data Published J Clin Oncol. 2013 Apr 1;31(10):1324-8 2-CED Published Lancet Oncol 2014 Oct;15(11):1215-23
Green	The Relationship between Semen Analysis and Treatment Exposures among SJLIFE Acute Lymphoblastic Leukemia Participants	Zhu Chemaitilly Sklar Kutteh Ke Pui Srivastava Metzger Hudson Robison	Wang, M	To assess the effect of cranial radiotherapy on the relative risk for oligospermia and azoospermia in ALL survivors	SJLIFE participants who are ALL survivors and were treated with prophylactic CRT	05/11/2015		SIOP 2016		Hum Reprod. 2017 Jun 1;32(6):1192-1201
Gurney	Bone Mineral Density Loss in Adult Survivors of Childhood Acute Lymphoid Leukemia	Chemaitilly Ness Srivastava Hudson Robison		To determine the trajectory of volumetric trabecular bone mineral density change using serial measures from quantitative computed tomography in 651 adult survivors of childhood ALL who are enrolled in the SJLIFE Study	ALL survivors who had at least one prior QCT	08/24/2011 Paper				Pediatr Blood Cancer. 61(7):1270-6, 2014
Gurney	Association of Bone Mineral Density, Cardiovascular Morbidity and Abdominal Aortic Calcifications	Ojha Ness Huang Sharma Kaste Hudson Robison	Huang	To investigate the association between abdominal aortic calcifications, BMD and CV risk factors	ALL survivors who completed QCT	09/27/2010 Paper	BIMS 4272			Pediatr Blood Cancer. 2012;59(7):1307-9

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Im	Genome-Wide Study of Late Effects of Therapy in Childhood Cancer Survivors (FP00003121)	Wilson Ness Kaste Hudson Robison Chemaitilly Yasui	Li, Z	To identify SNPs associates with low BMD	ALL survivors genotyped using SNP6.0 array	Reviewed GWAS Working group 03/02/2015				Published Hum Genet. 2018 Jan 18.
Inaba / Wilson	Body Composition among Adult Survivors of Acute Lymphoblastic Leukemia	Ness Kaste Hudson Robison Chemaitilly Pui	TBD	Describe relative proportions of visceral adipose tissue, subcutaneous adipose tissue and lean tissue mass in ALL survivors using qCT data, correlating to other markers of body composition in ALL survivors and investigating associations with treatment outcomes and long-term physical health outcomes.	ALL survivors in SJLIFE 18 y/o and older at qCT measurement	5/18/2020			6/2019	Prelim. data analysis in progress
Joyce/ Kaste	Association of Muscle Strength and Bone Mineral Density in Adult Survivors of Childhood Acute Lymphoblastic Leukemia	Ness Nolan Hudson Pui Ferry Robison Srivastava	Nolan	To describe associations between muscle strength and BMD among ALL survivors	ALL survivors who had a DEXA and a functional assessment as of 04/30/2010	01/19/2010 Paper	Done	NA		Archives Physical Med Rehab_ 92(6):873-9, 2011
Krull	Neurocognitive Outcomes of Adult Survivors of Childhood Acute Lymphoblastic Leukemia: Impact of Growth Hormone Deficiency (GHD)	Chemaitilly Armstrong Brinkman Cheung Gajjar Hudson Khan Kun Merchant Pui Robison Sabin Sklar Srivastava Vuotto Wilson	Li, C.	To assess the effect of GHD on neurocognitive and neurobehavioral outcomes in survivors of ALL treated with CRT and who do not have evidence of any other endocrine dysfunctions	SJLIFE participants are ALL survivors, were treated with prophylactic CRT and had no evidence of any endocrine dysfunctions other than GHD	05/11/2015	2015ER01 BIMS 5309	SIOP2016		Cancer. 2019 May 15;125(10):1748-1755.
Morgan Schuetz	Leydig Cell Function Following Treatment with 6-MP And Methotrexate	Green Chemaitilly Hudson Robison		To assess the effect of 6-MP and methotrexate on Leydig cell function using in-vitro and in-vivo models	SJLIFE participants with Leydig cell failure with exposures to 6-MP and methotrexate but no history of treatment with alkylating agents and testicular radiotherapy					Sci Rep. 2015 Nov 18;5:16488

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Morris	Are Low IGF-I Levels in Adult Survivors of ALL Associated with Diminished Vitality and/or Reduced Exercise Capacity?	Morris Li Hudson Robison Ness	Li	To evaluate the association between IGF-I serum levels, sense of vitality, and exercise capacity among a group of ALL survivors previously exposed to cranial irradiation	ALL survivors who completed SJLIFE visit as of February 28, 2010 and who were in blocks 1-32	August 2008 Paper	Done	Edinburg h 2009 (Morris)		Combined with pituitary concept
Ness/ Chemaitilly	Feasibility Study Evaluating the Acceptability and Initial Response to Growth Hormone (rDNA Origin) Replacement (GROWTH)					01/06/2009 Paper				Withdrawn.
van Iersel van Santen Chemaitilly	Prevalence, Risk Factors and Clinical Consequences of Hypopituitarism in Childhood Cancer Survivors: A SJLIFE Report	Li Ness Brinkman Wilson Green Merchant Armstrong Gajjar Srivastava Pui Hudson Robison Sklar	Li	<p>To describe the prevalence of GHD, TSHD, ACTHD, LH/FSHD and CPP in cranially irradiated and non-cranially irradiated childhood cancer survivors (brain tumor and non-brain tumor survivors).</p> <p>To test in univariable and multivariable models the effect of demographic variables, treatment variables and brain injury on HP disorders.</p> <p>To test in univariable and multivariable models the effect of HP disorders (present versus absent) on clinical outcomes.</p>	SJLIFE participants who have completed a campus visit	11/13/2017	2017ER03			Published J Clin Endocrinol Metab. 2019 Aug 2. pii: jc.2019-00834. doi: 10.1210/jc.2019-00834

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Wilson Varedi Ness	Body Composition Phenotypes in Pediatric Cancer Survivors	Hyun Chemaitilly Hudson Robison Armstrong Wilson Kaste Ehrhardt Mulrooney Green van Iersel Srivastava	Hyun	To determine the prevalence of body composition phenotypes overall, and by diagnosis To determine the prevalence of changes in body composition phenotype from first DEXA scan to the subsequent visits To identify associations between body composition phenotypes, secondary malignancies, and new onset endocrine, cardiovascular, fitness and mortality outcomes. To identify potential risk factors for "high adiposity/low muscular mass" phenotypes To identify associations between body composition phenotypes and body image perception at baseline	SJLIFE participants who have completed a campus visit	6/12/2018			2020	Additional analyses underway to update the longitudinal component (Wilson)
Williams	Diabetes Mellitus among Adult Survivors of Childhood ALL	Ness Howell Chemaitilly Wilson Nolan Smeltzer Green Karol Ehrhardt Pui Hudson Robison	TBD	To describe the types of diabetes mellitus and its prevalence and risk factors in SJLIFE participants with a history of ALL and identify potential genetic predisposition markers	SJLIFE participants with history of ALL who completed campus visit	1/23/2017	2017ER01			Cancer2020 Feb 15;126(4):870-878. doi: 10.1002/cncr.32596
Wilson	Modifiable Risk Factors Associated with Aging Phenotypes Among Survivors of Childhood Cancer	Kaste Hudson Gurney Srivastava Robison	Jones, K Srivastava	To assess the association between lifestyle factors and hormonal status and the prevalence of low BMD and frailty among ALL survivors	ALL survivors among SJLife participants	11/14/2011 Paper			4/2013	J Clin Oncol. 2016; 34(21):2509-15

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Wilson	Body Composition Among Adult Survivors of Abdominal and Pelvic Childhood Tumors	Lukens Wilson Hudson Srivastava Robison Lucas Ness	Liu	<ul style="list-style-type: none"> - To characterize body composition - To identify host- and treatment-related risk factors associated with low lean body mass and high percent body fat - To assess if low lean body mass is associated with a decreased physical function and with metabolic dysfunction 	SJLIFE participants previously treated for abdominal or pelvic solid tumors	10/27/2014 Paper	2014ER03 BIMS 5297	ESPE 9-2016		Cancer Epidemiol Biomarkers Prev. 2020 Aug 13. doi: 10.1158/1055-9965.EPI-19-1321
Wilson	Predicting Low BMD Among Survivors of Childhood Cancer	Hudson Ness Kaste Ojha Robison Chemaitilly Vanden Heuvel-Eibrink Pluijm Den Hoedt	Jones, K	To develop a prediction model for low BMD and validate prediction in an independent cohort of Dutch CCS.	<ul style="list-style-type: none"> - SJLIFE participants through to block 82 who underwent a DXA scan - Dutch Survivor Cohort validation cohort 	05/19/2014 Paper	2014ER01	Poster ASHG 2016; SIOP 2017		JCO. 2019 Sep 1;37(25):2217-2225.
Wilson/Ness	Genome-Wide Study of Late Effects of Therapy in Childhood Cancer Survivors (FP00003121)	Hudson Neale Robison Gurney Kang Ojha Yang	Liu Srivastava	To identify SNPs associated with obesity using a genome-wide association study approach	SJLIFE participants who have provided a blood sample	01/24/2011 Paper	BIMS 4322			Cancer. 2015 Jul 1;121(13):2262-70
Yoshida/ Delaney and Yasui	Adult growth hormone deficiency and physical, psychological, quality of life, and neurocognitive outcomes in childhood cancer survivors: A Report from the St. Jude Lifetime Cohort study	Yu Ness Wilson Mulrooney Brinkman Huang Kaste Krull Robison Hudson	Baedke	To assess the association between GH treatment and chronic health conditions (physical/psychological/QOL/n eurocognitive outcomes) in childhood cancer survivors.	SJLIFE participants who have completed a campus visit at ≥ 18 years of age; excluding those with neurodevelopmental d/o or neurologic injury (all aims), or without available IGF-1 measurement or with liver fibrosis/cirrhosis (from analyses involving IGF-1)	CCSP 5/2/2022				Analysis in progress

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Alvarado/Ness	The Inflammatory Potential of Diet Among Childhood Cancer Survivors and Metabolic and Psychological Outcomes: St. Jude Lifetime Study (SJLIFE)	Salehabadi Hebert Wirth Adams Ortaglia Chemaitilly Mulrooney Dixon Brinkman Lancot Williams Robison Hudson Ness	Kumar Srivastava, Emily Finch,	- To estimate and compare Dietary inflammatory Index (DII) scores among childhood cancer survivors and controls in the St. Jude Life cohort. Estimate changes in DII scores among CCS over time. - Compare and contrast the DII to the Alternate Healthy Eating Index (AHEI). - Investigate associations between host and treatment characteristics and DII scores - Investigate the cross-sectional and longitudinal associations between DII scores and markers of inflammation and metabolic health among childhood cancer survivors - Identify the cross-sectional and longitudinal associations between DII scores and adverse health outcomes (CVD, depression, and anxiety) among childhood cancer survivors and controls	≥18 SJLIFE participants	1/6/2020				Data analysis in process. Analyses are nearly complete. Data are with Dr. Alvarado for write up.

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Baassiri/Bhatt	Outcomes of Adult Survivors of Childhood Acute Myeloid Leukemia	Ehrhardt Ness Brinkman Krull Chemaitilly Armstrong Srivastava Robison Green Rubnitz Inaba Mulrooney Hudson	Srivastava Liu	<ul style="list-style-type: none"> - Estimate the prevalence of chronic health conditions among AML survivors in the SJLIFE cohort. - Describe the prevalence of subsequent neoplasms (benign and malignant) among AML survivors in the SJLIFE cohort. - Evaluate neurocognitive function among survivors of AML in the SJLIFE cohort. - Assess health-related quality of life (HRQOL) and their associations with treatment exposures among survivors of AML in the SJLIFE cohort: - Assess frailty measures and their associations with treatment exposures among survivors of AML in the SJLIFE cohort: - Estimate the prevalence of and the risk factors for physical performance limitations among survivors of AML in the SJLIFE cohort: - Assess emotional functioning and social attainment among survivors of AML in the SJLIFE cohort 	To be eligible a subject must 1) have received therapy for AML at St. Jude Children's Research Hospital, 2) be ≥ 10 years from diagnosis, 3) be ≥ 18 years old at time of evaluation, and 4) have completed a comprehensive risk-based health evaluation on the SJCRH campus 5) Living after 2007	11/23/2015	EB201603 BIMS 5310	SIOP 2016	06/2015	Leukemia. 2021 Jan 25. Online ahead of print
Bhakta	Cumulative Burden of Cardiovascular Morbidity in Paediatric, Adolescent, and Young Adult Survivors of Hodgkin's Lymphoma: An Analysis from the St Jude Lifetime Cohort Study	Zhu Li, Z Srivastava Huang, I Hudson Yasui Robison	Liu Yasui	Describe the average number of CTCAE grades 1-4 and grades 3-4 adverse events in the SJLIFE cohort using the MCC methodology as a function of (a) time from cancer diagnosis and (b) age.		03/31/2015	2015EB01	ASCO 2016	06/2015	Lancet Oncol 2016 Sept;17(9):1325-1334

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Bhakta	The Cumulative Burden of Surviving Childhood Cancer: An Initial Report from the St. Jude Lifetime Cohort Study (SJLIFE)	Liu Ness Baassiri Eissa Yeo Chemaitilly Ehrhardt Bass Bishop Shelton Lu Huang Li Caron Lanctot Howell Folse Joshi Green Mulrooney Armstrong Krull Brinkman Khan Srivastava Hudson Yasui Robison	Liu	- To describe the cumulative burden of curative cancer therapy in a clinically assessed ageing population of long-term survivors of childhood cancer	All patients in the SJLIFE population				June 2015	Lancet. 2017 Dec 9;390(10112):25 69-2582.
Bhakta	Estimating the Late Effect Disease Burden among Childhood Cancer Survivors using Quality Adjusted Life Years	Huang Li Srivastava Hudson Robison Wong	Li	- To Estimate childhood cancer survivor population specific utility weights using definitions from the SJLIFE modified CTCAE scoring system. - Calculate both total and outcome-specific QALYs in SJLIFE using Monte-Carlo simulation methods.	SJLIFE Cohort, but starting with Hodgkin survivors	5/15/15		ASH 2019		Primary Hodgkin manuscript in development

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Bhakta/Huang	Association Between Disease Burden and HRQOL in the SJLIFE Cohort	Ehrhardt Ness Krull Brinkman Srivastava Ganz Yasui Hudson Robison Huang	Liu	<ul style="list-style-type: none"> - Examine associations between cumulative burden & HRQOL among childhood cancer survivors - To identify latent classes of long-term childhood cancer survivors based on treatment exposure and CHC outcomes 	All SJLIFE 18+ 10+ year survivors with 10 MN who completed campus visit and the SF-36	3/20/2016	2017GO01	ASCO 2017		Aim 1 and 3 presented at ASCO. Aim 2 analysis completed. Manuscript in preparation.
Bhakta/Yasui	A Personalized Cumulative Burden Tool with Morbidities Adjusted for Health Utility	Liu, Q Yasui Huang, I Wong Hudson Robison		<ul style="list-style-type: none"> - Develop a series of independent models using demographic and exposure predictors to estimate the cumulative burden for groups of clinically similar CHCs over time in order to provide a total cumulative burden profile for any combination of predictors. - Incorporate the patient perspective by adjusting cumulative burden curves using health-related quality of life utility estimates. 	Incorporated into 2015 global freeze and for objective 2, have completed an SF36 survey	11/14/2016	2016GO02		June 2015	Methodology draft completed, 2nd round revisions ongoing. Analysis completed for cardiac outcomes. Additional analysis for all other outcomes ongoing. Platform built, iterative improvements ongoing.
Bhakta/Yasui	Multimorbidity/Cumulative Burden (R01)	Bhakta Yasui		<ul style="list-style-type: none"> - Build a measure of age/time-specific multimorbidity at the individual level that improves the existing cumulative burden methodology, using a clinical cohort of 9138 5-year survivors of childhood cancer, by: (1) enabling prediction of personalized multimorbidity, over various stages of the life-course, based on risk factors; and (2) integrating patient perspectives into the analytic output by creating condition-specific "burden weights." 						Scored 8 th percentile – pending council review

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Bhakta/Yasui	Incorporating Survivorship into Global Burden of Disease (planned R01 submission)	Bhakta Yasui		- Quantify the excess burden of disease associated with surviving childhood cancer for 24 childhood cancers in 204 countries and territories from 1990 to 2020, using mortality, years of life lost (YLLs), years lived with disability (YLDs), and disability-adjusted life years (DALYs). We will account for the increased risk of comorbidities due to cancer-related treatments and their impact on the quality of life, and the continuing excess mortality in childhood cancer survivors. Disability weights obtained from data collected from long-term survivorship cohorts will be used to estimate the morbidity associated with surviving childhood cancer.						Planned submission 2022
Bishop/Mulrooney	Cumulative Burden of Chronic Health Conditions in Adult Survivors of Osteosarcoma and Ewing Sarcoma: A Report from SJLIFE	Ness Li Liu Srivastava Chemaitilly Krull Green Pappo Robison Hudson Mulrooney	Li Liu	- To characterize cumulative burden and prevalence of chronic health conditions as well as physical and neurocognitive performance among adult survivors of childhood bone sarcomas.	≥18 year old SJLIFE participants					CEBP. 2020 Aug 29(8):1627-1638
Bjornard/Howell	Comparison of Treatment of Pediatric Cancer Survivors Across Four National Cohorts, Between 1970-1999	Kiri Ness Kumar Srivastava Yutaka Yasui Les Robison Melissa Hudson Matt Ehrhardt	Howell Chen	- To examine the generalizability of the SJLIFE cohort to the US population of childhood cancer survivors in terms of basic treatment modalities	SJLIFE Cohort	09/25/2017	2017G001			Decided not to pursue this initiative.

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Ehrhardt	Late Outcomes of Adult Survivors of Childhood Non-Hodgkin Lymphoma	Sandlund Ness Brinkman Krull Chemaitilly Kun Kaste Armstrong Zhang Srivastava Green Robison Hudson Mulrooney	Liu	Aim 1 - Estimate the incidence of and identify risk factors for chronic health conditions among NHL survivors in the SJLIFE cohort Aim 2 - Estimate the incidence of and identify risk factors for subsequent neoplasms (benign and malignant) among NHL survivors in the SJLIFE cohort Aim 3 - Estimate the prevalence of and risk factors for clinically significant physical performance limitations among NHL survivors	Subjects must 1) have received therapy for NHL at St. Jude Children's Research Hospital, 2) be ≥ 10 years from diagnosis, 3) be ≥ 18 years old at time of evaluation, and 4) have completed a comprehensive risk-based health evaluation on the SJCRH campus	08/18/2014	BIMS 5065 2014EB01	ASCO 2015	06/2015	Pediatr Blood Cancer. 2017 Jun;64(6)
Ehrhardt	Breast Cancer Risk and Detection in Female Childhood Cancer Survivors in the St. Jude Lifetime Cohort Study (SJLIFE)	Howell, C. Hale Baassiri Rodriguez Wilson Joshi Lemond Shope Howell, R. Wang Srivastava Mulrooney Zhang Robison Ness Hudson	Howell	- To describe the characteristics of and risk factors for breast cancers detected in female survivors of childhood cancer - To compare the diagnostic accuracies of mammography and magnetic resonance imaging (MRI) in the detection of breast cancer in a subset of women within SJLIFE who received both modalities as part of risk-based screening.	SJLIFE Cohort			SIOP 2018	06/2015	JCO. Jul 1;37(19):1647-1656
Ehrhardt/Hudson	Optimizing Stratified Cancer Survivorship Care Through Multimorbidity Risk Prediction.	Bhakta Liu Robison Yasui Hudson	Liu	- Develop risk-prediction models based on cumulative burden to identify low-, moderate-, and high-tier CHC burden profiles to risk-stratify follow-up. - Identify the fewest variables required to inform risk models. - Identify impact of HRQoL on risk prediction for tiered care.	All SJLIFE eligible participants					Supplemental funding awarded under SJLIFE U01 2020. Data collection and cleaning underway.

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Ehrhardt/Hudson	Modifiable Risk Factors for Overall and Cause-Specific Mortality in Childhood Cancer Survivors in the St. Jude Lifetime Cohort Study (SJLIFE)	Dixon Armstrong Bhakta Brinkman Caron Chemaitilly Mulrooney Ness Redd Robison Shelton Srivastava Yasui Hudson	Pending	- Describe overall and cause-specific mortality rates in childhood cancer survivors in the SJLIFE cohort. - Examine the effects of modifiable risk factors on overall and cause-specific mortality rates in childhood cancer survivors.	Aim 1 – all participants and non-participants (living and deceased) eligible for SJLIFE Aim2 – All participants in SJLIFE who have completed a systematic health evaluation at SJCRH	1/6/2020				Manuscript draft nearly completed, anticipate circulation to co-authors in next 2 weeks, SIOP 2022 and ISLCCC abstracts submitted
Ehrhardt/Hudson	Cumulative Burden in Young Adult Childhood Cancer Survivors in SJLIFE at Key Healthcare Transitions	Liu Scholle Bhakta Hudson	Liu	- Describe cumulative burden in childhood cancer survivors at ages 18 and 26.	≥18 SJLIFE participants	N/A				Pediatr Blood Cancer. 2021 Jun 68(6):e29030
Eissa/Ness	Outcomes of Survivors Treated with HCT	Hudson Robison Mulrooney Triplett Brinkman Krull Chemaitilly Phipps Srivastava Huang Rubinitz Bhakta	Lu	Explore medical and functional outcomes among aging survivors of HCT compared to those treated without HCT	Leukemia lymphoma survivors in SJLIFE treated post 1/1/1982	03/31/2015		ASBMT 2017	06/2015	Blood Adv. 2017 Nov 7;1(24):2243-2246
Foster/Mulrooney	Late Outcomes of Survivors of Childhood Wilms Tumor	Green Davidoff Krasin Brennan Krull Brinkman Chemaitilly Ehrhardt Ness Hudson Mulrooney	Xing	- Describe the prevalence and cumulative burden of chronic health conditions, incidence of SNs, late neurocognitive performance, clinically significant physical performance limitations, social attainment, emotional functioning, HRQoL, and fertility/pregnancy in adult survivors of Wilms in SJLIFE.	Wilms survivors in SJLIFE who have completed a comprehensive health evaluation at SJCRH.	1/27/2020		ASCO 2021		Manuscript submitted to Pediatrics Feb 2022. Invited to revise and resubmit – in process.

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Goggin/Wolf	Following Results of Oncologic Therapy: Long-term Outcomes of Pediatric Sepsis (FROOT LOOPS)	Goggin Ehrhardt Howell Brinkman Ness Krull Bhakta Srivastava Robison Hudson Wolf	Lu Lu	- To compare the incidence of ≥ 1 grade 3-5 sepsis-associated chronic condition, in survivors who did or did not experienced severe sepsis during treatment. - To quantify neurocognitive sequelae, functional performance, and HRQOL among the SJLIFE cohort to validate previous finding of relationship with sepsis during treatment for ALL. To compare both the frequency of common outcomes and the burden of chronic disease in each individual organ system between survivors with and without sepsis during treatment.	SJLIFE Cohort	7/30/2017			06/2017	Manuscript in preparation.
Green	Hepatic Damage after Treatment for Childhood Cancer	Relling Srivastava Ness Kaste Krasin Greene Pui Jeha Bishop Furman Fernandez-Pineda Robison Hudson		- Estimate the prevalence of abnormal liver function, estimated by AST and ALT, in survivors of childhood cancer - Identify factors associated with an increased risk of abnormal liver function in survivors	All patients in the SJLIFE population	04/18/2016	BIMS 5397 2016GO01	ASCO 2017	June 2015	Hepatology. 2019 Jan;69(1):94-106

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Guida/Ness	Estimation of Biological Aging Among Childhood Cancer Survivors in SJLIFE	Belsky Gallicchio Green Wang Wilson Yasui Hudson Armstrong Robison Ness	Geehong Huang	<ul style="list-style-type: none"> - Estimate biological age using physiology-based and DNA-methylation-based measures for childhood cancer survivors, community controls, and the US population from the NHANES III dataset. - Determine if older biological age is associated with quicker progression to frailty and death in post-treatment survivors. - Assess the impact of baseline social and lifestyle factors on biological age at follow-up in childhood cancer survivors. 	SJLIFE participants who completed an on-campus assessment and have biomarker data available.	4/06/2020				Analysis complete – manuscript being drafted
Howell/ Bjornard	Evolution and Expansion of the St. Jude Lifetime Cohort Study, 2007-2016	Kiri Ness Kumar Srivastava Yutaka Yasui Les Robison Melissa Hudson Matt Ehrhardt	Howell	<ul style="list-style-type: none"> - To describe the demographic and treatment related characteristics and predictors of participation in the current expanded SJLIFE cohort - To examine demographic and treatment related predictors of participation in the current expanded SJLIFE cohort, potential participation bias in the expanded SJLIFE cohort by comparing the frequency of demographic and treatment related characteristics among participants of SJLIFE to the overall pool of eligible participants, and generalizability of the SJLIFE cohort to the US population of childhood cancer survivors in terms of demographics, diagnosis groups, and basic treatment modalities 	SJLIFE Cohort	09/25/2017	2017GO02		March 12, 2020 (special update)	Int J Epidemiol. 2021 Mar 50(1):39-49.

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Howell/Ness	Neighborhood Effects on Obesity in Adult Survivors of Pediatric Cancer: a Report from the St. Jude Lifetime Cohort Study	Wilson Yasui Srivastava Lu, W Bjornard Ehrhardt Brinkman Chemaitilly Lancot Robison Hudson	Howell	To explore the associations between neighborhood effects, physical activity, diet, smoking, treatment intensity, demographics and obesity in adult survivors of childhood cancer and among controls with no history of childhood cancer	Survivors and controls with a campus visit between 2010 and 2016 and have available address for geocoding	11/20/2017			2016	Int J Cancer. 2019 Oct; Epub ahead of print.
Huang/Schwartz	Response-Shift Effects in Future Health Expectations Among Long-Term Adult Survivors of Childhood Cancer: A Report from St. Jude Lifetime Cohort Study	Sim Poudel Srivastava Ness Hudson Robison Baker		Identify specific types of response-shift effects among long-term adult survivors of childhood cancer who experience worsened global burden of chronic health conditions over the survivorship trajectory				ISOQOL 2021		MS being drafted (40% complete)
Hudson	Approach for Classification and Severity-grading of Long-term and Late-onset Health Events among Childhood Cancer Survivors in the St. Jude Lifetime Cohort.	Ehrhardt Bhakta Baassiri Eissa Chemaitilly Green Mulrooney Armstrong Brinkman Klosky Krull Sabin Wilson, C. Huang Bass Hale Kaste Khan Srivastava Yasui Joshi Srinivasan Stokes Hoehn Wilson, M. Ness Robison	NA	- Explain the CTCAE criteria in SJLIFE	NA					Cancer Epidemiol Biomarkers Prev. 2017 May;26(5):666-674

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Hudson/ Ness	Yield from Risk-Based Screening in Adults Treated for Cancer in Childhood	Nolan Armstrong Green Gurney Krull Spunt Metzger Srivastava Robison	Ness Srivastava	To determine prevalence of previously undetected cancer-related toxicities in survivors evaluated by risk-based health screening	All potentially eligible survivors as of Block 59	07/07/2009 11/19/2009 Paper	BIMS 4307 2009EB05	ASCO 2010	Oct 2012	JAMA. 2013;309(22):23 71-2381
Hudson/Crom	Childhood Cancer Survivors Workplace Experiences (SJLA2)	Brinkman Ness	Ness	To estimate the degree of work discrimination in young adult cancer survivors.	First 500 participants in SJLIFE with history of current or previous employment	02/24/2009	2009EB01		N/A	J Cancer Surviv. 2018 Aug;12(4):469- 478
Karlage/ Ness	Body Composition in Long-Term Childhood Cancer Survivors: Applicability of Anthropometric Measures	Kaste Huang Green Armstrong Robison Laver Hudson	Zhang	To determine if current anthropometric measures accurately predict body composition using DXA as gold standard	SJLIFE participants who completed functional assessment and DXA scan	01/10/2011 Paper	BIMS 4347 2011EB01	Abstract accepted Williamsburg 2012	April 2013	Cancer. 2015;121(12):20 36-43
Kimberg	Remote Neurocognitive Assessment in Adult Survivors of Childhood Cancer	Robison Hudson Krull	Li Srivastava	To examine the association between remote telephone-based assessment, web-based assessment and traditional on-site neuropsychological assessment	SJLIFE survivors treated with CRT or antimetabolite chemotherapy	07/30/2008 Paper	2011EB03		N/A	No paper planned
Krull/I-Chan	Patient-Reported Outcomes Measurement Tools and Clinical Application for Childhood Cancer Survivors.	Hudson Gurney Ness Robison Brinkman Shenkman Quinn Li	Huang	To develop and validate a patient-reported outcomes (PROs) tool for young adult survivors of childhood cancer using item response theory methodology	SJLIFE and ACT patients 18-45 with IQ> 79	06/13/2011 Paper	2011EB02			J Clin Oncol. 2013;31(33): 4242-4251

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Mulrooney	Late Outcomes of Adult Survivors of Childhood Acute Lymphoblastic Leukemia	Ness Brinkman Krull Chemaitilly Kun Armstrong Srivastava Relling Pui Jeha Sandlund Green Robison Hudson		<ul style="list-style-type: none"> - Evaluate the prevalence of chronic health conditions among ALL survivors in the SJLIFE cohort. - Describe the incidence of subsequent neoplasms (benign and malignant) among ALL survivors in the SJLIFE cohort - Describe late neurocognitive performance among survivors of ALL. - Describe clinically significant physical performance limitations among ALL survivors in the SJLIFE cohort 	Subjects must 1) have received therapy for ALL at St. Jude Children's Research Hospital; 2) be ≥ 10 years from diagnosis; 3) be ≥ 18 years old at time of evaluation; 4) have completed a comprehensive risk-based health evaluation on the SJCRH campus	07/08/2013	2013EB01	ASCO 2015	June 2014	Lancet Haematol. 2019 Jun; 6(6):e306-316
Nolan	QOL Prediction Validation Using CCSS and SJLIFE Data		Ness			CCSS Proposal	2011EB03		April 2013	Pediatr Blood Cancer. 2014;61(10):1891-1894
Ojha/Gurney	Participation Versus Non-Participation in SJLIFE: Comparative Analysis and Risk Prediction Model	Oancea Ness Lancot Robison Hudson	Srivastava	To perform descriptive analyses to characterize participants and non-participants in the SJLIFE cohort and develop a statistical prediction model to help screen eligible SJLIFE participants.	SJLIFE eligible	03/12/2012	2012EB02			Pediatr Blood Cancer. 2013;60(5):856-864
Park	Nutrition, Dietary Patterns, And Risk of Frailty in Adult Survivors Of Childhood Cancer	Park Jiang Colditz Williams Ness Foley Lancot Krull Hudson Robison	Park	- To investigate associations between dietary components and dietary patterns and frailty in SJLIFE survivors.	≥ 18 SJLIFE participants who have completed a dietary assessment and measures to calculate the deficit accumulation index.	3/2/2021				Analysis in process. First analyses of associations between nutrients, food and dietary patterns and frailty done
Salerno/Ness	Characterizing Physiologic Frailty in Younger Childhood Cancer Survivors: A Report From SJLIFE	Williams Park Krull Waters Hudson Ehrhardt Ness		<ul style="list-style-type: none"> - Develop frailty indices in SJLIFE survivors <18 y/o. - Determine predictive validity of these indices for all-cause mortality and QOL. - Identify behavioral and demographic predictors of frailty in SJLIFE survivors <18. 	≥ 18 SJLIFE participants who have completed measures to calculate the deficit accumulation index.	5/4/2021				Data provided to Dr. Salerno. Analysis underway

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Schwartz/Ness	The Impact of Neighborhood Socioeconomic Status On Frailty In Childhood Cancer Survivors	Howell Brinkman Ehrhardt Delaney Srivastava Lanctot Armstrong Robison Hudson Henderson	Dhudak	-Describe the association between development of frail and pre-frail states as they relate to neighborhood socioeconomic status for childhood cancer survivors. -Identify the direct and indirect effects of different cancer treatment exposures on the relationship between frailty and neighborhood socioeconomic status in childhood cancer survivors. --Examine the prevalence of chronic health conditions as well as their possible direct and indirect effects on the relationship between frailty and neighborhood socioeconomic status in childhood cancer	SJLIFE participants ages ≥18 years			SIOP 2021 – oral Award Section	12/31/2018	Manuscript draft completed – revisions done – should circulate to co-authors this week
Strauser/Ness	Childhood Cancer Survivors Workplace Experiences (SJLA2)	Hudson Brinkman Klosky Ojha	Huang Srivastava	To estimate the degree of career readiness in young adult cancer survivors.	First 500 participants in SJLIFE with history of current or previous employment	01/27/2009 02/24/2009 Paper	2009EB01		N/A	J Cancer Surviv. 2015;9(1):20-9
Talbot/Ness	Functional Outcomes After Pelvic Bone Resections for Bone Sarcomas.	Talbot Neel Ehrhardt Ness		- Evaluate functional outcomes in SJLIFE survivors who had pelvic bone tumors involving the acetabulum.						Concept under development
Ware/Ness	Characterizing Exceptional Survivorship	Ehrhardt Bhakta Armstrong Yasui Srivastava Salehabadi	Not assigned yet	-To determine the characteristics of survivors who do not develop adverse outcomes when they have known treatment exposures associated with chronic conditions						Concept in development - presented in WG – revisions being made
Ware/Ness	Health Disparities in Survival Among St. Jude Children's Research Hospital Childhood Cancer Patients		Wang	-To assess the role of SES on five- and ten-year survival disparities in SJCRH patients. -To assess the role of health insurance coverage on five- and ten-year survival disparities in SJCRH patients.						Approved by CCSP – analysis underway

CCSP CONCEPT/ANCILLARY STUDY REGISTRY Global/Biostatistics/ Epidemiology Working Group										Working Group Co-Chairs: Matt Ehrhardt, Kiri Ness, & Kumar Srivastava
WG update: May 26, 2022										
Principal Investigator/ Senior Mentor	Concept Title	Co-Investigators	Statistician / Analyst	Objective	Eligibility Criteria	Date CPC Investigator Review/Type	BIMS#/ SJLIFE#	Abstract	Date of Data Freeze	Analysis/ Manuscript Progress
Williams/Krull	Aging-Related Deficit Accumulation in Survivors of Childhood Cancer	Mandelblatt Ness Armstrong Bhakta Brinkman Chemaitilly Ehrhardt Mulrooney Small Wang Yasui Hudson Robison Krull	Srivastava/ Mingjuan Wang	-To characterize aging in childhood cancer survivors as an accumulation of deficits and compare it to community controls. -Examine associations between treatment/clinical factors and social determinants of health with the aging-related DAI. -Examine associations between the aging-related DAI and neurocognitive impairment, sleep, and mortality. -Examine the association between the aging-related DAI with epigenetic age acceleration and telomere length. -In survivors with >1 SJLIFE visit, characterize the change and longitudinal trajectory of aging-related DAI and examine its association with subsequent outcomes (mortality, cognition, poor sleep). -Compare the aging-related DAI in SJLIFE survivors to breast cancer survivors in the Thinking and Living with Cancer study (TLC).	All SJLIFE participants	06/22/2020		ASCO 2021		submission to JAMA Oncol Feb 2022
Wilson/Ness	Genome-Wide Study of Late Effects of Therapy in Childhood Cancer Survivors (FP00003121)	Hudson Neale Robison Gurney	Liu Srivastava	To identify SNPs associated with the incidence of obesity late effects using a genome-wide association study approach	SJLIFE participants who have provided a blood sample	01/24/2011 Paper	BIMS 4322 2011EB04		April 2013	Cancer. 2015;121(13):22 62-2270
Yeh	Morbidity and Mortality Data request – validation for a CCSS project		Kyla preparing data	to use the SJLIFE data for all eligible to validate a simulation model is based on CCSS data (excluding SJLIFE participants) - projects the risk of developing 8 chronic conditions and excess mortality risks over the lifetime of survivors.	All eligible SJLIFE participants				April 2020	Data request received. DUA preparation underway

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Zhu	Statistical Methodology Development for GWAS Analysis of Recurrent-event Data in Cancer Study	Ji, L. Li, Y. Yasui Bhatia Srivastava Armstrong Hudson Robison		Develop a semiparametric method with proportional mean model for GWAS analysis of recurrent-event data on each SNP, test it by simulation studies and apply it to the CCSS data Develop a pathway analyses method for recurrent event phenotype/outcome and applied to CCSS data, and validate the results in SJLIFE data - Develop implementation procedures and an R package for the statistical techniques developed in objectives 1 - 2 for the wide application of the research results	SJLIFE participants with SNP data				June 2016	R01 was not funded – considering resubmission.

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Alexander/ Gandy	Brain Volume Loss and Neuroinflammation After Intrathecal Methotrexate and Oral Dexamethasone in a Juvenile Mouse Model of Childhood ALL Chemotherapy	David-Goodrum Charlton Steinberg Vavere Akers Nieman Krull		<ul style="list-style-type: none"> - Measure structural changes in brains of juvenile mice treated with MTX and DEX shortly after chemotherapy. - Assess long-term effects of MTX and DEX on regional brain volume via MRI. - PET imaging of neuroinflammation with TSPO tracer - Ex vivo overnight scanning rapid acquisition with relaxation enhancement (RARE) MRI. 	P21 juvenile mice	IACUC 652-199632	NA		NA	Protocol approved by IACUC. Data collection is ongoing.
Alexander	Associations Between Metabolic Syndrome and Neurocognitive Function in Long-Term Survivors Of Childhood Cancer	Dixon Williams, A Chemaitilly Brinkman Mulrooney Ness Banerjee Srivastava Robison Hudson Krull	Liu Srivastava	<ul style="list-style-type: none"> - To evaluate associations between metabolic syndrome (Yes/No) with neurocognitive impairment and quality of life in long-term survivors of childhood cancer, stratified by history of CNS-directed cancer therapy. - To examine associations between the type and number of metabolic syndrome conditions (hypertension, hypertriglyceridemia, abdominal obesity, low HDL, high fasting glucose) with neurocognitive impairment in survivors treated with and without CNS-directed therapy. - To explore direct and indirect effects of cancer therapy through metabolic syndrome conditions on neurocognitive outcomes in long-term survivors of childhood cancer, stratified by history of CNS-directed therapy. 	Participants in SJLIFE (2019 freeze) Survivors treated with CNS-directed therapies: - Intrathecal chemotherapy - Cranial radiation - Neurosurgery Survivors not treated with CNS-directed therapies Community Controls Completed neurocognitive testing	5/4/2020	BIMS 6236	Oral presentation at ASCO 2021	2019	Manuscript rejected from Annals of Internal Medicine;

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Armstrong	Long-Term Treatment Related CNS Injury in Survivors of Childhood ALL (CNSRI)	Krull Sabin Reddick Ogg Hudson Robison	Zhang Srivastava	To evaluate prevalence of long-term memory deficits (dementia) and MRI correlates	SJLIFE survivor of ALL exposed to cranial RT	2009 Grant 11/26/2012	2009NS05 BIMS 4430	Aim 2 - SIOP 2012 Aim 1 – ASH 2012 Late Effects 2013 Tractography abstract to HBM		Funded: Recruitment completed. Aim 1: J Natl Cancer Inst. 2013; 105(12):899-907 Aim 2: Blood. 2013; 122(4):550-3
Banerjee	Memory Function and Symptoms of Sleep Apnea in Long-Term Survivors of Childhood Hodgkin Lymphoma	Mandrell Brinkman Cheung Robison Hudson Sabin Krull	Srivastava	To examine associations between memory symptoms of sleep apnea in long-term survivors of childhood Hodgkin lymphoma treated with thoracic radiation	SJLIFE survivors diagnosed with Hodgkin lymphoma and treated with thoracic radiation; sleep with partner	11/29/2012 BRIGHT IRB		ICCTF 2016 SIOP 2016		Additional analyses for sample. Withdrawn
Banerjee	Total Neurocognitive Burden in Long-Term Survivors of Childhood Cancer	Yasui Tonning Olsson Bhakta Brinkman Huang Khan Armstrong Srivastava Robison Hudson Krull	Liu Srivastava	To identify the total burden of neurocognitive impairment in adult survivors of childhood cancer; and examine associations with treatment-related predictors and psychosocial/QOL outcomes	Adult SJLIFE participants who received neurocognitive testing	05/01/2017 Paper	5664	INS 2019 SIOP 2020 INS 2021	2016	Manuscript drafted.
Bass	The Long-Term Trajectory of Auditory Function of SJCRH Patients Treated for Extremity Osteosarcoma or Neuroblastoma	White Ness Santana Furman Navid Hudson Robison Green	Dhaduk Srivastava	To describe and compare frequency and time course of hearing loss in patients treated with cis-platin compared to carboplatin	Ages 0 – 17 at Rx; treated for extremity osteosarcoma or neuroblastoma; ≥ 3 years survival after initiation of active cancer therapy	02/14/2011 Paper	BIMS 4531 2011NS01			Analyses ongoing
Bass	Effect of Sensorineural Hearing Loss on Neurocognition in Childhood Cancer Survivors Treated with Platinum-Based Chemotherapy	Banerjee Brinkman Li Mulrooney Schreiber Srivastava Robison Hudson Krull	Liu, W. Srivastava	To assess the impact of significant SNHL on neurocognitive outcomes among SJLIFE participants treated with cisplatin, carboplatin, and/or cranial RT for CNS and non-CNS cancers	Survivors treated with cisplatin and/or carboplatin who received audiological and neurocognitive evaluations per the SJLIFE protocol	02/13/2017 Paper			2016	JAMA Oncol. 2020; 6(9):1-9.

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Bass	Comprehensive Grading System for Reporting Ototoxicity in Children Treated with Cranial Radiation Therapy with or without Platinum Chemotherapy.	Yock Ness Jones Hua Merchant Gajjar Srivastava Robison Hudson	Xing Salehabadi	<ul style="list-style-type: none"> - To validate the COMP Ototoxicity Grading Scale in SJLIFE patients treated with cranial radiotherapy with and without platinum-based chemotherapy for CNS cancers by comparing the scale to existing criteria: CTCAE v4.03, Chang, and SIOP criteria. - Evaluate the association between COMP ototoxicity grade and audiological recommendations for intervention. - Evaluate inter-rater reliability of the COMP ototoxicity scale. 	SJLIFE participants previously treated with cranial radiation therapy with and without cisplatin and/or carboplatin who received audiological evaluations per the SJLIFE protocol.					Analyses complete. Manuscript being drafted.
Bass	Evaluation of cochlear implant candidacy in survivors of childhood cancer	Warren Patterson Sander Golden Peeples Richard Krull Srivastava Robison Hudson		<ul style="list-style-type: none"> - Estimate the prevalence of survivors of childhood cancer with severe to profound SNHL who meet criteria for a CICE. - Explore potential risk factors for survivors meeting criteria for a CICE. 	SJLIFE participants who received audiological evaluations per the SJLIFE protocol.	NSWG 4/8/2022				
Brinkman	Neurocognitive Functioning in Long-Term Survivors of Pediatric Brain Tumors	Krull Sadighi Hudson Gurney Armstrong Gajjar Robison Merchant	Liu Srivastava	To characterize neurocognitive function in long-term survivors of CNS tumors	SJLIFE participants with CNS tumors who completed neurocognitive assessment	11/22/2010 Paper	2010NS01 BIMS 4292	ASCO 2012 ISPNO 2012 INS 2013		J Clin Oncol. 2016;34(12):1358-67
Brinkman	Cerebral White Matter Integrity and Executive Function in Adult Survivors of Childhood Medulloblastoma	Reddick Sabin Srivastava Robison Hudson Krull	Srivastava	To explore brain white matter integrity in long-term survivors of childhood medulloblastoma	SJLIFE participants enrolled in HPP7					Neuro Oncol. 2012 14(4) 25-36.

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Brinkman	Neurocognitive Functioning in Long-Term Survivors of Retinoblastoma	Krull Gurney Merchant Wilson Phipps Qaddomi Armstrong Hoehn Brennan Robison Hudson	Li Srivastava	- To examine neurocognitive functions in long-term RB survivors - To identify associations with disease/treatment exposure variables	SJLIFE participants with RB who completed neurocognitive assessment	11/22/2010 Paper	BIMS 4292 2010NS02	ASPHO 2011		Cancer. 2015;121(1):123-31
Brinkman	Sleep-Based Intervention for Neurocognitive Deficits in SJLIFE Cohort MIND	Krull Mandrell Banerjee Robison Hudson	Li, C. Srivastava	To examine the impact of melatonin compared to placebo on neurocognitive function	- SJLIFE participant - IQ > 79; - Treatment with cranial RT or antimetabolites; - Neurocog deficits; - Sleep impairment	04/25/2011 05/23/2011 Paper	2011NS02 BIMS 5184	SIOP 2016		Pediatr Blood Cancer. 2021 Jul;68(7):e28988. Support Care Cancer. <i>In press.</i>
Brinkman	Effect of Treatment-Induced Hearing Loss on Social Outcomes in Adult Survivors of Childhood Cancer	Bass Ness Spunt Hudson Brinkman Merchant Armstrong Gajjar Srivastava Gurney	Li, Z. Srivastava	To describe the prevalence of hearing loss and the distribution by severity of auditory impairment among SJLIFE participants exposed to platinum-based chemotherapy and/or cranial radiation	SJLIFE participants previously treated with cisplatin, carboplatin, and/or cranial radiation, and who received audiologic evaluations.	06/13/2011 Paper	2011NS04	<u>ESLCCC 2011</u>		Cancer. 2015;121(22):4053-61

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Brinkman/Krull	Neurostimulation in Adult Survivors of Childhood Leukemia	Banerjee Hudson Kesler Mandrell Phillips Reddick Robison Sabin Scoggins Sitaram Srivastava	Srivastava	To evaluate the efficacy of home-based transcranial direct current stimulation (tDCS) paired with remote cognitive training on direct testing of executive function in survivors of ALL. To examine the effects of home-based tDCS paired with remote cognitive training on patterns of regional brain activation as measured by functional magnetic resonance imaging. To examine the effects of home-based tDCS paired with remote cognitive training on white matter integrity and structure as measured by diffusion tensor imaging.	<ul style="list-style-type: none"> Completed treatment for acute lymphoblastic leukemia (ALL) at SJCRH < 21 years at diagnosis; currently between 18 and 39 years of age; ≥ 5 years post-diagnosis English language proficiency Executive dysfunction defined as having an age-adjusted standard score <16th percentile on Trail Making Test Part B, Verbal Fluency, or Digit Span Backward Patient-reported executive dysfunction defined as a standard score >84th percentile on the Childhood Cancer Survivor Study Neurocognitive Questionnaire 	IRB Approved			NA	NEUROSTIM NIH funded. Data collection ongoing.
Brinkman	Change in Neurocognitive Functioning during Adulthood in Long-Term Survivors of Childhood Cancer: A Longitudinal Report from the St. Jude Lifetime Cohort Study	Banerjee Alexander Phillips Williams Ehrhardt Brinkman Ness Mulrooney Srivastava Robison Hudson Krull	Liu Srivastava	<ul style="list-style-type: none"> - To examine change in neurocognitive function in long-term survivors of childhood cancer survivors (primarily ALL and CNS tumor) from initial to follow-up SJLIFE assessment. - To determine demographic and treatment-related predictors of neurocognitive change. - To examine associations between chronic health conditions and neurocognitive change. <p>To examine associations between health behavior and neurocognitive change.</p>	<ul style="list-style-type: none"> Adult survivors of childhood ALL Age ≥18 years Received neurocognitive testing at least twice (not including any post-intervention visits) per the SJLIFE protocol 	9/23/19	6250	Abstract submitted to INS 2022	2018	Analyses ongoing

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Cheung	Genome-Wide Association Study of Stroke in Survivors of Childhood Cancer Who Received Cranial Radiation	Sapkota Tinkle Khan Wilson Yasui Srivastava Banerjee Hudson Robison Krull	Cheung Sapkota Srivastava	To conduct a Genome-Wide Association Study (GWAS) within the St Jude Lifetime Cohort Study (SJLIFE) cohort to systemically identify single nucleotide polymorphisms (SNPs) in genes that affect stroke risk in this population	Survivors in SJLIFE with DNA genotyped; Treated with CRT; Cases: - Survivors with a graded stroke event “Cerebrovascular accident” “Cerebrovascular disease” and/or “Intracranial hemorrhage”, based on CTCAE version 4.03 Controls: - Survivors without a graded stroke event	05/16/2016	2016NS01			Null results.
Cheung	Uric Acid and Neurocognitive Function in Adult Survivors of Childhood Acute Lymphoblastic Leukemia	Mulrooney Brinkman Kimberg Chemaitilly Gurney Green Robison Hudson Krull	Li, C. Srivastava	- To examine associations between uric acid and neurocognitive performance in adult survivors of childhood ALL - To explore whether the effects of uric acid on neurocognitive function are mediated by renal, cardiovascular, and metabolic factors	- SJLIFE participants diagnosed with childhood ALL; - Participants must have undergone neurocognitive evaluation; - Biomarkers of interest must be available near time of evaluation (within 72 hours)	12/17/2012	2012CA05			Cancer Epidemiol Biomarkers Prev. 2016; 25(8):1259-67
Edelmann	Diffusion Tensor Imaging and Neurocognitive Performance in Long-Term Adult Survivors of Childhood ALL	Sabin Glass Robison Hudson Krull Reddick	Liu Srivastava	To examine the association between DTI parameters and results of neurocognitive testing in long-term adult survivors of childhood ALL.	ALL survivors enrolled on SJLIF7 or SJLIF13	12/10/2010	2010NS03 BIMS 4311	ASNR June 2011		Brain. 2014; 137(Pt 11):2973-83
Edelmann	Cognitive, Psychosocial, and Quality of Life Outcomes in Adult Survivors of Childhood Osteosarcoma	Brinkman Kimberg Robison Hudson Mulrooney Ness Bishop Krull	Liu Srivastava	Describe neurocognitive, emotional, social, and quality of life outcomes in adult survivors of childhood osteosarcoma	SJLIFE participants diagnosed with childhood osteosarcoma and treated with HDMTX	12/09/2013	2013NS01 BIMS 4930			JAMA Oncol. 2016; 2(2): 201-8

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Ehrhardt	Neurocognitive, Psychosocial, and Quality of Life Outcomes in Adult Survivors of Childhood Non-Hodgkin Lymphoma	Mulrooney Sandlund Brinkman Huang Srivastava Ness Robison Hudson Krull	Srivastava Li	<ul style="list-style-type: none"> - Describe the neurocognitive, emotional, social, and quality of life outcomes in adult survivors of childhood NHL - Examine the effects of treatment and patient characteristics on neurocognitive, emotional, and/or quality of life outcomes - Examine whether impairment in neurocognitive function is related to educational attainment, employment status, and/or quality of life outcomes 	SJLIFE participants diagnosed with NHL and Community Controls	02/09/2015	2015NS01	Submitted to ASH 2016		Cancer. 2018 Jan 15;124(2):417-425
Elmuti/Phillips	Exercise and Neurocognitive Outcomes in Hodgkin Lymphoma Survivors	Ness Krull	Wogksch	<ul style="list-style-type: none"> - Describe the prevalence of low VO2 max (<85% predicted) among survivors compared to controls and identify demographic, treatment and CTCAE conditions associated with low VO2 max. - Describe prevalence of autonomic dysfunction (AD) among survivors compared to controls and identify demographic and treatment factors associated with AD. - Examine associations between AD, and VO2max and neurocognitive outcomes among survivors. - Explore if VO2 max mediates interaction between demographic, treatment, chronic conditions identified in SA 1, and neurocognitive outcomes. - Explore if AD mediates interaction between treatment, demographics, VO2 max and neurocognitive outcomes. 	-					Analysis in progress

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Gandy	Genetic Variants, Brain Integrity, and Neurocognitive Outcomes in Long-term Survivors of Childhood Hodgkin Lymphoma Treated with Thoracic Radiation	Phillips Williams, A Wang Sapkota Srivastava Mulrooney Ehrhardt Reddick Ness Robison Hudson Mandrell Sabin Krull		Aim 1: To examine genetic associations with white matter brain integrity in long-term survivors of childhood HL. Aim 2: To determine if genetic associations are related to neurocognitive outcomes in long-term survivors of childhood HL. Exploratory Aim: To explore associations between brain integrity, neurocognitive function, and genetic variants known to be associated with cardiopulmonary disorders, attention deficits, and memory impairments.	Inclusion Criteria: 1. Enrolled in the SJLIFE cohort. 2. Enrolled in the BRIGHT or APNEA study protocol. 3. Diagnosed with childhood HL. Exclusion Criteria: 1. History of head injury or genetic disorder associated with neurocognitive impairment. 2. History of secondary central nervous system neoplasms. 3. History of congenital heart disease.	11/29/21				Analyses ongoing
Gurney	Evaluation of Motor and Sensory Neuropathy Associated with Vincristine and Platinum Drug Exposure in SJLIFE Solid Tumor Survivors	Ness Spunt Hudson Srivastava Robison	Jones Srivastava	To describe and quantify the types and degrees of motor and sensory neuropathic symptoms and related impairments in adult survivors of childhood solid tumors who were treated with vincristine or platinum drug.	SJLIFE participants treated for solid tumors and tested in Ness's Performance Lab (excluding brain tumors)	05/23/2011 Paper	2011NS03			Arch Phys Med Rehabil. 2013;94(8):1451-1457
Kimberg	Neurocognitive Function as a Predictor of Adherence to Medical Care in Adult Survivors of ALL	Brinkman Klosky Robison Hudson Krull	Zhang	To examine the association between neurocognitive function and adherence to medical care in ALL survivors	SJLIFE ALL survivors who completed neurocognitive evaluations and who were expected to obtain follow-up care outside SJCRH prior to their visit	04/23/2012	2012NS3 BIMS 4584			Cancer. 2015;121(5):774-82
Krull	Neurocognitive Rehabilitation in Adult Survivors of Childhood Cancer	Brinkman Jones Stewart Studaway Robison Hudson	Srivastava	To examine the impact of cognitive skill training on neurocognitive functioning in long-term survivors	SJLIFE survivors treated with CRT or antimetabolite chemotherapy	03/31/2010 Ancillary study	2011NS06 None	13 th Late Effects Conference 2013		Analyses complete; results being used for grant development

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Krull	FDG PET in Adult Survivors of Childhood Cancer Treated with Cranial Radiation	Sulkin Minoshima Brinkman Edelmann Sabin Armstrong Robison Hudson		To examine patterns of FDG PET activation associated with neurocognitive function	Survivors enrolled in SJLIF7	12/10/2010 Paper	BIMS 4311	INS 2013 CNS 2013		J Nucl Med. 2014;55(11):1805-10
Krull	Executive Function Outcomes in Adult Survivors of Pediatric Leukemia	Armstrong Pui Gurney Ness Robison Hudson	Li Srivastava	To examine patterns of executive dysfunction in adult survivors of childhood ALL	SJLIFE survivors of ALL with no CNS relapse	02/21/2011 Paper	BIMS 4056 2011NS07	ASH 2010 INS 2011		J Clin Oncol. 2013; 31(35):4407-15
Krull	The Impact of Growth Hormone Deficiency on Neurocognitive Function in Adult Survivors of Childhood Acute Lymphoblastic Leukemia Treated with Cranial Radiation	Chemaitilly Li Cheung Brinkman Wilson Armstrong Khan Sabin Srivastava Merchant Pui Robison Hudson Sklar	Li, C. Srivastava	To examine associations between growth hormone deficiency and neurocognitive outcomes in adult survivors of childhood cancer	Survivors of ALL treated with CRT	05/11/2015		SIOP 2016		Cancer. 2019 May 15;125(10):1748-1755.

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Krull	Healthy Kids After Cancer: A Physical Activity and Nutrition Intervention	Hudson Brinkman Jones Kimberg Lewis Stewart Studaway Banerjee		To evaluate the feasibility, acceptability, and potential efficacy of a portable, parent-targeted, phone-delivered nutrition and physical activity program to prevent unhealthy weight gain among childhood ALL survivors 4 to 10 years old who are 1-5 years post chemotherapy	<ul style="list-style-type: none"> - Between 4.0 years and < 11.0 years of age at recruitment; - Previously diagnosed of ALL and currently in remission; - Between 2-5 years post completion of chemotherapy; - BMI > 85 percentile for age and sex (overweight or obese) OR at risk for obesity (BMI between the 50th and 85th percentile and at least one overweight parent (BMI > 25 kg/m2) 	03/27/2015 HKAC IRB				Approved & activated; funded by R21 from NIH; Analyses completed. Manuscript revision resubmitted.
Krull	Cerebrospinal Fluid Biomarkers of Long-Term Neurocognitive and Brain Imaging Outcomes in Survivors of Childhood Lymphoblastic Leukemia Treated with Chemotherapy	Alexander Niu Phillips Jacola Reddick Jeha Yasui Peng	Yasui	To characterize the CSF proteome at diagnosis and during ALL chemotherapy. To examine associations between CSF proteome and neurocognitive and brain imaging outcomes at end of therapy.	<ul style="list-style-type: none"> - Survivors enrolled on Total 16. - No relapse or CRT 					Funded by V Foundation; analyses ongoing.
Krull	Brain Aging in Survivors of Hodgkin Lymphoma Treated with Thoracic Radiation	Gandy Williams Reddick Sabin Kesler Ness Scoggins Wang Yasui Robison Hudson	Yasui	To estimate accelerated brain aging in survivors treated with thoracic radiation. To examine associations between accelerated brain age and serum biomarkers of aging. To examine associations between accelerated brain age and neurocognitive function.	Hodgkin lymphoma survivors enrolled on BRIGHT and/or APNEA. Community controls enrolled on BRIGHT or APNEA					Funded by NCI Administrative Supplement. MRI brain aging completed. Biomarkers being processed.

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Krull	Brain Aging in Survivors of ALL and CNS Tumors	Gandy Williams Reddick Sabin Kesler Ness Scoggins Wang Yasui Robison Hudson	Yasui	To estimate accelerated brain aging in survivors of ALL and CNS tumor. To examine associations between accelerated brain age and serum biomarkers of aging. To examine associaitons between accelerated brain age and neurocognitive function.	ALL and CNS tumor enrolled in SJLIFE with prior brain MRI. Community controls enrolled on BRIGHT or APNEA					Funded by NCI Administrative Supplement. MRI brain aging completed. Biomarkers being processed.
Krull	Characterizing Sleep Among Long-term Survivors of Childhood Cancer	Gandy Lubas Mandrell Phillips Wang Mulrooney Ness Armstrong Crabtree Salehabadi Robison Hudson Brinkman	Salehabadi	To characterize the sleep using polysomnography and PROs across broad diagnosis groups in SJLIFE.	SJLIFE survivors diagnosed with ALL, CNS tumor or Solid tumors.					8/17/21 Pilot study approved by CTSRC and biostats committee.

Krull	Risk for Psychopathology and Neurocognitive Impairment in Leukemia Survivors (NEULS)	Cheung Reddick Brinkman Ogg Srivastava Robison Pui Hudson	Liu Srivastava	To identify mechanisms of neurocognitive and psychosocial impairment in long-term survivors of ALL	Survivors treated on Total 15. No history of CRT.	IRB 2009				<p>Funded by NIMH R01.</p> <ul style="list-style-type: none"> - 1st manuscript <i>JCO</i> 2016; 34(22): 2644-53. - 2nd manuscript <i>Lancet Haematol</i> 2016; 3(10): e456-66. - 3rd manuscript <i>Psychoneuroendo</i> 2017; 76: 114-18. - 4th manuscript <i>Cancer</i> 2017; 123(17): 3410-19. - 5th manuscript <i>JAMA Oncol</i> 2018 4(7). - 6th manuscript <i>J Cancer Surviv</i> 2018; 12(3): 398-406. - 7th manuscript <i>Psychooncol</i> 2018 27(6) 1597-1607. - 8th manuscript <i>Psychooncol</i> 2018 27(8) 2031-38. - 9th manuscript <i>JAMA Pediat</i> 2018 172(11) 1092-1095. - 10th manuscript <i>Brain Connect</i> 2018 8(6) 333-42. - 11th manuscript <i>Am J Neuroradiol</i> 2018 39(10) 1919-25. - 12th manuscript <i>J Natl Cancer Inst</i> 2019 111(2) 201-09. - 13th manuscript <i>JAMA Oncol</i> 2019 5(10) 1456-63. - 14th manuscript <i>Pediat Blood Cancer</i> 2020 67(3). - 15th manuscript <i>JAMA Oncol</i> 2020 6(1) 158-59.
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WG update: August 24, 2022			CCSP CONCEPT/ANCILLARY STUDY REGISTRY Neuroscience Working Group				Working Group Chair: Kevin Krull & Ranga Sitaram			
Principal Investigator/ Senior Mentor	Concept Title	Co-Investigators	Statistician/ Analyst	Objective	Eligibility Criteria	Date CPC Investigator Review/Type	BIMS#/ SJLIFE#	Abstract	Date of Data Freeze	Analysis/ Manuscript Progress
										<ul style="list-style-type: none"> - 16th manuscript JAMA Netw 2020 3(11). - 17th manuscript Cancer 2021 Apr 29 - 18th manuscript JNCI Cancer Spectrum 2022 - 19th manuscript Planned submission to JNCI 2022 (Genetics & fMRI) - 20th manuscript Planned submission to Brain Connectivity 2022 (MDS approach to fMRI connectivity)
Krull/Liu	Feasibility and Efficacy of Transcranial Direct Current Stimulation (tDCS) and Cognitive Training for Executive Dysfunction in Adult Survivors of Childhood Acute Lymphoblastic Leukemia	Hudson Brinkman Banerjee Lewis Butler Stewart Jones Studaway	Srivastava Liu	To evaluate the influence of tDCS To evaluate the feasibility of a home-based intervention using tDCS and cognitive stimulation in adult survivors of childhood ALL participating in the SJLIFE study	<ul style="list-style-type: none"> - Current St. Jude LIFE Participant - Long term survivor of (ALL) - Currently ≥ 18 years of age - Wi-Fi internet access at home - History of executive dysfunction - Participant is able to speak and understand the English language 	12/16/2014 ALLSTIM IRB	BIMS 4998			Manuscript under review.
Krull/Mandrell	Subjective and Objective Sleep Findings Among Survivors of Childhood Hodgkin Lymphoma	West Morris Ness Robison Sabin Hudson Banerjee	Liu Srivastava	To examine the impact of sleep quality in adult survivors of Hodgkin Lymphoma	Survivors enrolled on SJLIF16	12/15/2009 08/24/2010 02/28/2011 Paper 09/23/2013	2009NS03	ASMRC June 2010		Pilot study extended. Funded through BRIGHT supplement. Manuscript submitted to <i>Sleep</i> (2 nd journal).

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Krull/Mandrell	Sleep Apnea in Survivors of Childhood Cancer Treated with Thoracic Radiation	Mulrooney Sabin Reddick Hillenbrand Srivastava Banerjee Hudson Ness	Liu Srivastava	To examine prevalence and predictors of polysomnography identified OSA in adult survivors of childhood cancer treated with thoracic radiation therapy	SJLIFE Hodgkin lymphoma survivors treated with thoracic radiation. Community controls frequency matched on age, sex, race/ethnicity and BMI.					Funded through APNEA R01. Data collection in process.
Krull/Sabin	Brain Integrity in Survivors of Childhood Cancer Treated with Thoracic Radiation	Reddick Ness Mulrooney Khan Williams Krasin Robison Hudson Sabin Krull	Liu Srivastava	To evaluate brain integrity in adult survivors of childhood cancer treated with thoracic radiation therapy. To identify therapeutic factors associated with brain integrity in adult survivors of childhood cancer who are at risk for cardiac and pulmonary morbidity. To examine associations between cardiac vascular and pulmonary health and brain integrity in adult survivors of childhood cancer treated with thoracic radiation.	SJLIFE Hodgkin lymphoma survivors treated with thoracic radiation. Community controls frequency matched on age, sex and race/ethnicity.			Oral Presentation ICCTF 2020 (AMW) Poster Presentation ASH 2019	NA	Funded by BRIGHT R01. - 1st manuscript drafted - 2nd manuscript in progress. - 3rd manuscript submitted <i>JNCI</i> .
Krull/Sitaram	Brain aging and neuroinflammation in long-term survivors of childhood cancer	Armstrong Bag Bagga Gandy Hudson Ness Phillips Reddick Robison Sabin Scoggins Shulkin Vavere Wang	Srivastava	To collect pilot data on associations between molecular, morphologic and functional connectivity indices of brain aging in long-term survivors of childhood cancer. To explore associations between indices of brain aging and hematologic biomarkers in long-term survivors of childhood cancer. To explore associations between indices of brain aging and neurocognitive function.	CNS tumor (medulloblastoma), ALL (CRT vs Chemo-only), HL (chest RT) Participation in brain aging supplement/					Protocol in development

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Principal Investigator/ Senior Mentor	Concept Title	Co-Investigators	Statistician/ Analyst	Objective	Eligibility Criteria	Date CPC Investigator Review/Type	BIMS#/ SJLIFE#	Abstract	Date of Data Freeze	Analysis/ Manuscript Progress
Mulrooney	The Feasibility of Preventative Atorvastatin Use in Adult Childhood Cancer Survivors Treated with Neck Radiation: A Pilot Study	Zabrowski Banerjee Robison Hudson Alexandrov Krull Khan	Srivastava	<ul style="list-style-type: none"> - To study the feasibility of statin use in adult survivors of childhood cancer - To study the natural history of atherosclerosis in adult survivors of childhood cancer treated with chest and neck radiation - To estimate changes in neurocognitive function in survivors using statins 	<ul style="list-style-type: none"> - Adult survivors of childhood Hodgkin lymphoma treated with chest and neck radiation - ≥ 18 years of age - ≥ 10 years from initial cancer diagnosis 	05/16/2016	2016NS02			Returned to CTSRC. ON HOLD
Ness	Motor Proficiency and Physical Activity in Adult Survivors of Childhood ALL (MTRPAL)	Lanctot Hudson Robinson Srivastava Kaste Baker DeLany	Huang	To enumerate the prevalence of musculoskeletal, sensory, and fitness impairments among adult survivors of childhood ALL	ALL survivors 18 years old or older who are 10 years from dx and not currently undergoing treatment for cancer	2008 Grant	2008NS01 None			<ul style="list-style-type: none"> - 1st manuscript Blood.2015;125(22):3411-3419 - 2nd manuscript Phys Ther. 2016; 26(7): 1029-38 - 3rd manuscript Cancer. 2019 Oct 21. Epub ahead of print. - 4th manuscript Cancer. 2018 Mar 1;124(5):1036-1043 - 5th manuscript J Clin Oncol. 2018 Aug 1;36(22):2315-2322 - 6th manuscript Pediatric Blood Cancer; 2018 Jul 29:e27286. - 7th manuscript - 8th manuscript New manuscript Cancer 2020. 126(3) 640-648

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Principal Investigator/ Senior Mentor	Concept Title	Co-Investigators	Statistician/ Analyst	Objective	Eligibility Criteria	Date CPC Investigator Review/Type	BIMS#/ SJLIFE#	Abstract	Date of Data Freeze	Analysis/ Manuscript Progress
Ness	A Longitudinal Assessment of Frailty in Young Adult Survivors of Childhood Cancer	Armstrong Brinkman Folse Kaste Krull Lancot Mulrooney Srivastava Robison Hudson		Evaluate the change in the proportion of young adult cancer survivors who are frail from baseline to a point five years later; evaluate the association between frailty and worsening of chronic health conditions; describe the association between demographic and treatment factors and risk for prevalent frailty; estimate the effects of physical activity, diet and smoking on risk for prevalent frailty	Participants enrolled in SJLIFE	01/23/2012		R01 funded Poster ASCO 2020 (AMW)		Funded by FRAILTY R01. - 1st manuscript <i>J Natl Cancer Inst</i> 2021 Mar 15. - 2nd manuscript <i>JCO</i> 2021 Jul 20. -
Ness	Physiologic Frailty in Adult Survivors of Childhood Cancer	Krull Brinkman Armstrong Robison Hudson	Jones Srivastava	To assess declining physical performance as a function of age in the SJLIFE cohort	Participants enrolled in SJLIFE	01/23/2012	2011NS10 None	Paper		J Clin Oncol. 2013; 31(36):4496-503
Ness	Performance-Based Physical Function in Long-Term Survivors of Pediatric Hodgkin Lymphoma	Metzger Huang Armstrong Robison Hudson	Ness	To characterize physical performance limitations among adult survivors of HL and identify host and treatment related predictors of poor outcomes	Survivors of HL who complete HPL assessment	Pending Paper	2011NS09 None	ASCO 2011 ACSM abstract May 2015	2015	Pediatr Blood Cancer. 2019 Mar;66(3):e27506.
Oancea	Pathways Linking Treatment Effect and Psychological Distress Among Long-Term Survivors of Childhood Cancer: Results from the St. Jude Lifetime Study	Krull Ness Klosky Srivastava Huang Robison Hudson Gurney Brinkman	Oancea Gurney	To evaluate the potential socioeconomic and health related mediators and moderators of the association between childhood cancer treatment effect and psychological distress in adult survivors of childhood cancer	SJLIFE	09/17/2012 Paper				2 aims complete J Cancer Surviv. 2014; 8:293–303

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Principal Investigator/ Senior Mentor	Concept Title	Co-Investigators	Statistician/ Analyst	Objective	Eligibility Criteria	Date CPC Investigator Review/Type	BIMS#/ SJLIFE#	Abstract	Date of Data Freeze	Analysis/ Manuscript Progress
Papini	Neurocognitive Outcomes in Neuroblastoma	Tonning Olsson Wilson Banerjee Partin Santana Furman Henderson Diller Green Mulrooney Srivastava Robison Hudson Ness Krull Brinkman	Wang Srivastava	To estimate the prevalence of neurocognitive impairment in adult survivors of neuroblastoma. To examine demographic and treatment factors associated with neurocognitive impairment. To evaluate associations between chronic health conditions (e.g., cardiopulmonary, hearing loss) and neurocognitive impairment. To examine associations between neurocognitive impairment and social attainment and health related quality of life.	SJLIFE participants diagnosed with neuroblastoma					Analyses ongoing
Papini	tDCS and Mindfulness Intervention for Chronic Pain	Krull Brinkman	Srivastava	To estimate potential impact of tDCS vs mindfulness training in treatment of chronic pain	SJLIFE participants with chronic pain					Approved in NSWG
Phillips	Subcortical Brain Volumes and Neurocognitive Function in Survivors of Childhood Acute Lymphoblastic Leukemia (ALL) treated with Chemotherapy-only.	Glass Scoggins Cheung Liu Ogg Mulrooney Pui Robison Reddick Hudson Krull	Phillips Liu	To examine association between subcortical brain volumes, treatment exposures and neurocognitive function in survivors of ALL treated with chemotherapy only	NEULS IRB	Paper		ASCO 2017 Late Effects 2017		Pediatr Blood Cancer. 2019 Aug 12:e27968.
Phillips	Susceptibility Weighted Imaging and Neurocognitive Performance in Long-Term Adult Survivors of Childhood ALL	Anderson Armstrong Robison Hudson Krull Sabin	Liu Srivastava	To examine the association between the number of foci of susceptibility change and neurocognitive performance	ALL survivors enrolled on SJLIF7 or SJLIF13	12/10/2010 Multiple Paper	2010NS04 BIMS 4311	ASNR June 2011 Abstract to North Carolina Medical Society 2014		Scientific Reports. 2020. 10(1) 692
Phillips	Cerebral Perfusion in Survivors of Hodgkin Lymphoma	Gandy Ness Hudson Krull	Liu, W	Determine if cerebral blood flow regulation is decoupled in HL survivors during exercise	>18 yo, >5 years from diagnosis of HL, treated with XRT					Approved by NSWG; ACS Application pending resubmission. R21 application submitted.
Phillips	Seizure Frequency and Associated Outcomes In SJLIFE	Khan Krull Edelmann Lewis Hudson Robison	Srivastava	To characterize pattern of seizures in SJLIFE and examine impact in functional outcomes	Survivors with seizure events following treatment	04/14/2014	<u>2014NS03</u> BIMS 4966	SIOP 2015		Accepted <i>Cancer</i> . 2021. Sept 1.

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Principal Investigator/ Senior Mentor	Concept Title	Co-Investigators	Statistician/ Analyst	Objective	Eligibility Criteria	Date CPC Investigator Review/Type	BIMS#/ SJLIFE#	Abstract	Date of Data Freeze	Analysis/ Manuscript Progress
Phillips	Transcranial Direct Current Stimulation of the Temporal Cortex in Survivors of Childhood All	Banerjee Mirzaei Krull Hudson Robison	Mirzaei	- Evaluate the feasibility and efficacy of using transcranial direct current stimulation in children who are long-term survivors of ALL	8-17.99 yo Diagnosis with ALL Chemotherapy only - IRB approved					Met goals for SA1, Recruiting for SA2
Phillips	Use of Brain Photo-biomodulation to Improve Cerebral Perfusion in Survivors of Childhood Cancer	Litten Krull		- To estimate feasibility of using PBM and NIRS in long-term survivors of childhood leukemia, Hodgkin's lymphoma, or brain tumor - To estimate the potential efficacy of powering a future larger study of the neurocognitive changes seen from PBM, based on the effect size from NIRS results - To compare the cerebral blood flow (CBF) in areas where PBM was administered of left and right frontal lobes of leukemia, Hodgkin's lymphoma, and brain tumor long-term survivors - To compare the population of C-reactive protein (CRP) the morning after PBM administration of left and right frontal lobes of leukemia, Hodgkin's lymphoma, and brain tumor long-term survivors	- Leukemia, Hodgkin's lymphoma, or brain tumor survivors who received chemotherapy, are enrolled in SJLIFE, and experience executive function deficiencies from direct testing - 15-39 years old - Equal number of males and females (but not by diagnosis) - MRI in the past 6 months that does not show malignancy of tumor					Approved by CTSRC Approved by IRB Pending activation

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Principal Investigator/ Senior Mentor	Concept Title	Co-Investigators	Statistician/ Analyst	Objective	Eligibility Criteria	Date CPC Investigator Review/Type	BIMS#/ SJLIFE#	Abstract	Date of Data Freeze	Analysis/ Manuscript Progress
Phillips	Extended Long-term Follow-up of memory and psychosocial outcomes in ALL survivors	Lui Glass Papini Gandy Reddick Jacola Ness Hudson Brinkman Krull	Darji	<ul style="list-style-type: none"> - Compare the size of the hippocampus, amygdala, fornix, and temporal lobe structures of survivors to controls. - Examine associations between size of hippocampus, amygdala, and temporal lobe structures of survivors and behavioral health outcomes. - Determine associations among brain hippocampal, parahippocampal, and fornix measures and future memory function. Explore associations between oppositional and obsessive behaviors during adolescence and memory problems during adult long-term follow-up. - Explore associations between oppositional and obsessive behaviors during adolescence and memory problems during adult long-term follow-up. - Explore associations between brain structure measures and oppositional and obsessive behaviors during adolescence with social attainment during adulthood. 	<ul style="list-style-type: none"> - Survivor of childhood ALL who participated in the NEULS protocol. - Survivor and control who had a compatible high resolution 3-D T1 brain scan collected as part of either NEULS or FNIMB1. - NEULS participants who returned for a SJLIFE neurocognitive evaluation that included the California Verbal Learning Test (CVLT) and completed the psychosocial surveys. 					Analysis in progress
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Principal Investigator/ Senior Mentor	Concept Title	Co-Investigators	Statistician/ Analyst	Objective	Eligibility Criteria	Date CPC Investigator Review/Type	BIMS#/ SJLIFE#	Abstract	Date of Data Freeze	Analysis/ Manuscript Progress
Sabin	Meningiomas on MRI Screening Among Long-Term Survivors of Childhood Cancer	Armstrong Santucci Hudson Krull Robison	Srivastava	Calculate prevalence of meningiomas among survivors of childhood cancer treated with cranial radiation compared to survivors who did not receive cranial radiation	SJLIFE survivors enrolled in SJLIF7, SJLIF13, SJLIF16 or CNSRI who have received MRI's	07/30/2012 Paper	2012NS4	ANSR May 2013		J Cancer Surviv. 2014; 8(3):329-35
Studaway	Neurocognitive and Quality of Life Outcomes of Chronic Hepatitis C Infection Among Adult Survivors of Childhood Cancer	Brinkman Ojha Banerjee Butler Robison Hudson Krull	Zhang Srivastava	To examine the association between chronic hepatitis C virus (HRCV) infection and neurocognitive function and health-related quality of life among adult survivors of childhood cancer	Survivors with blood transfusion prior to 1992	08/11/2014 SJLIFE		INS 2016		Cancer. 2017 Nov 15;123(22):4498-4505
Tonning Olsson	Neurocognitive Outcome In Survivors of Wilms Tumor	Brinkman Hyun Banerjee Mulrooney Huang Green Srivastava Robison Hudson Krull	Geehong Hyun	<ul style="list-style-type: none"> - To estimate the prevalence of cognitive impairment, poor quality of life, emotional distress, and low social attainment in adult survivors of WT, and associations to demographic and treatment factors and to chronic conditions; - To examine associations between cognitive impairment, social attainment and HRQOL 	SJLIFE participants with WT	02/20/17		INS 2018	2016	J Cancer Surviv. 2019 Aug;13(4):570-579. doi: 10.1007/s11764-019-00776-8. Epub 2019 Jun 26. PMID: 31243647
Tonning Olsson	Neurocognitive Outcome in Survivors of Soft Tissue Sarcoma	Brinkman Wang Banerjee Huang Ness Ehrhardt Mulrooney Bishop Robison Hudson Krull	Mingjuan Wang	<ul style="list-style-type: none"> - To estimate the prevalence of cognitive impairment, poor quality of life, emotional distress, and low social attainment in adult survivors of STS, and associations to demographic and treatment factors and to chronic conditions; - To examine associations between cognitive impairment, social attainment and HRQOL 	SJLIFE participants with STS	05/15/17		SIOP 2017	2016	Cancer 2020 126(7) 1576-84.

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Principal Investigator/ Senior Mentor	Concept Title	Co-Investigators	Statistician/ Analyst	Objective	Eligibility Criteria	Date CPC Investigator Review/Type	BIMS#/ SJLIFE#	Abstract	Date of Data Freeze	Analysis/ Manuscript Progress
Varedi/Ness	PCALL- Postural Control under Different Cognitive Loads in Adult Survivors of Acute Lymphoblastic Leukemia and Age-Matched Healthy Individuals			<ul style="list-style-type: none"> - To compare changes in postural control in ALL survivors to changes in postural control in healthy controls frequency matched on age- and sex- in simple versus complex standing and walking activities (complex: standing or walking with added cognitive load). - To identify demographic, treatment and performance related risk factors for decreased postural control during complex standing or walking activities in survivors. 	<ul style="list-style-type: none"> • Diagnosis of childhood ALL • At least 5 years post ALL diagnosis • Enrollment on the SJLIFE protocol • Age 18 to 39, including 18 years old and 39 years old individuals • Ability to speak and understand English • Ability to stand and walk for 20 seconds, multiple times 					Paper being drafted.
Williams AM	Association between Chronic Health Conditions and Neurocognitive Function in Long-term Survivors of Childhood Cancer	Ness Huang Yasui Ehrhardt Bhakta Banerjee Brinkman Green Mulrooney Chemaitilly Armstrong Hudson Robison Krull	Liu Srivastava	To evaluate the associations between CTCAE chronic health condition categories and neurocognitive outcomes in long-term survivors of childhood cancer, stratified by treatment with or without direct CNS-targeted therapies	SJLIFE survivors	05/02/2017 Paper		INS 2020 SJ Postdoc Symposium 2019	2017	Ann Neurol. 2021 Mar;89(3):534-545. doi: 10.1002/ana.25981. Epub 2020 Dec 31.
Williams AM	Aging-related Biomarkers of Neurocognitive Function in Childhood Cancer Survivors	Ness Wang Dong Liu Phillips Kunda Banerjee Sabin Yasui Robison Hudson Ehrhardt Krull	Li, Z. Srivastava	<p>To describe the association between telomere length, epigenetic age acceleration, and immune cell composition with neurocognitive functioning in SJLIFE.</p> <p>To describe the longitudinal association between biomarkers and neurocognitive function in HL survivors.</p>	SJLIFE survivors	April 2021 Funded by NCI K99R00				Analyses ongoing. Additional biomarkers being processed.

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Principal Investigator/ Senior Mentor	Concept Title	Co-Investigators	Statistician/ Analyst	Objective	Eligibility Criteria	Date CPC Investigator Review/Type	BIMS#/ SJLIFE#	Abstract	Date of Data Freeze	Analysis/ Manuscript Progress
Williams AM	Neuropathy and Neurocognitive Impairment in Long-term Survivors of Childhood Cancer	Phillips Goodenough Brinkman Papini Delaney Armstrong Allen Jacola Reddick Khan Robison Hudson Ness Krull		Examine the cross-sectional associations between peripheral (sensory and motor) and autonomic (cardiac) neuropathies and neurocognitive function. Among survivors with multiple visits, examine if persistent neuropathy or new onset neuropathy is associated with change in neurocognitive function. Using a structural equation framework, examine mechanistic (e.g., inflammation) psychological (e.g., pain) and health behavior (e.g., physical activity) pathways from neuropathy to neurocognitive impairment.	Inclusion criteria: i. Survivors of childhood cancer in SJLIFE ii. At least five years from diagnosis Exclusion criteria: iii. Genetic syndromes unrelated to cancer diagnosis and associated with cognitive impairment. iv. Neurodevelopmental disorder or neurologic injury unrelated to cancer diagnosis or treatment iv. Non-English speaking vi. Amputation vii.Paralysis	10/25/2021				

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Williams, AM/Krull	Aging-Related Deficit Accumulation in Survivors of Childhood Cancer	Mandelblatt Ness Armstrong Bhakta Brinkman Chemaitilly Ehrhardt Mulrooney Small Wang Yasui Hudson Robison Krull	Srivastava/ Mingjuan Wang	<p>-To characterize aging in childhood cancer survivors as an accumulation of deficits and compare it to community controls.</p> <p>-Among survivors, examine associations between treatment/clinical factors and social determinants of health (education, income, neighborhood SES, etc.) with the aging-related DAI.</p> <p>-Among survivors, examine associations between the aging-related DAI and neurocognitive impairment, sleep, and mortality.</p> <p>-Among survivors, examine the association between the aging-related DAI with epigenetic age acceleration and telomere length.</p> <p>-Among a subset of SJLIFE survivors with more than 1 visit, characterize the change and longitudinal trajectory of aging-related DAI and examine its association with subsequent outcomes (mortality, cognition, poor sleep).</p> <p>-Compare the aging-related DAI in SJLIFE survivors to breast cancer survivors in the Thinking and Living with Cancer study (TLC).</p>	All SJLIFE participants	06/22/2020		ASCO 2021	2020	<p>1st manuscript submitted to <i>JCO</i></p> <p>2nd manuscript being drafted</p> <p>3rd manuscript, analyses ongoing.</p>
Wilson	Long Term Complications of Adult Survivors of Childhood Neuroblastoma	McGregor Spunt Ness Bass Krull Gurney Hudson	Li Zhenghong	To describe the long term complications for adult survivors aged ≥ 18 years, whom are at least five years from diagnosis for childhood neuroblastoma utilizing medical assessments and self-reported questionnaires	SJLIFE participants with NB	01/23/2012	2012NS1			Cancer In press.

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Principal Investigator/ Senior Mentor	Concept Title	Co-Investigators	Statistician/ Analyst	Objective	Eligibility Criteria	Date CPC Investigator Review/Type	BIMS#/ SJLIFE#	Abstract	Date of Data Freeze	Analysis/ Manuscript Progress
Yoshida	Hypogonadism and Neurocognitive Outcomes Among Childhood Cancer Survivors	Alexander Chemaitilly Williams Lubas Banerjee Brinkman Robison Hudson Krull Delaney	Xing Salehabadi	<ul style="list-style-type: none"> - To update risk estimates and classification of hypogonadism in St Jude Life participants (comparing survivors to controls). - To determine neurocognitive outcomes in hypogonadal and eugonadal survivors. To explore potential risk factors for poorer cognitive outcomes among hypogonadal Survivors.	<ul style="list-style-type: none"> •Adult survivors of childhood cancers in SJLIFE (2018 freeze) •Completed neurocognitive testing •Survivors treated with CNS-directed therapies: <ul style="list-style-type: none"> -Intrathecal chemotherapy -Cranial radiation - Neurosurgery •Survivors not treated with CNS-directed therapies 	7/27/2020		Abstract submitted to INS 2022	2020	Analyses complete, manuscript being drafted
Zhang FF	Effect of Dietary Intake on Neurocognitive and Behavioral Outcomes in Adult Survivors of Childhood Cancer	Lanctot Brinkman Kimberg Chemaitilly Ness Ojha Robison Hudson Krull	Srivastava	To characterize the nutritional patterns of long-term survivors of childhood cancer and to examine the association between daily Caloric intake and neurocognitive outcomes in adult survivors of childhood cancer	<ul style="list-style-type: none"> - SJLIFE participants - Participants must have undergone neurocognitive evaluation - Participants must complete Food Frequency Questionnaire 	02/24/2014	2014NS02	INS February 2015		Analysis complete. Third ms in progress.

WG update: May 27, 2022										
CCSP CONCEPT/ANCILLARY STUDY REGISTRY Behavioral/Psychosocial Working Group						Working Group Chairs: Tara Brinkman & Rachel Webster				
Principal Investigator/ Senior Mentor	Concept Title	Co-Investigators	Statistician/ Analyst	Objective	Eligibility Criteria	Date CPC Investigator Review	BIMS#/ SJLIFE#	Abstract	Date of Data Freeze	Analysis/ Manuscript Progress
Alberts/ Brinkman	Intervention Use, Self-Medication, and Pain in Adult Survivors of Childhood Cancer	Allen Stinson Huang Ehrhardt Tonning Olsson Buckley Greene Spraker-Perlman Robison Hudson Anghelescu	Xing Mirzaei Salehabadi	<p><u>Aim 1:</u> To examine the prevalence of pharmacologic intervention use (nonopioid analgesic, opioids, medical marijuana), nonpharmacologic intervention use (physical therapy, biofeedback, hypnosis/guided imagery), CAM use (homeopathic remedies, crystals/magnets), and self-medication (illicit drug use, alcohol abuse, tobacco use) in the whole cohort of adult survivors of childhood cancer, in adult survivors of childhood cancer with elevated pain and pain interference, and in controls.</p> <p><u>Aim 2:</u> To identify demographic, psychological, and treatment-related factors associated with pharmacologic intervention use, nonpharmacologic intervention use, CAM use, and self-medication in the whole cohort of adult survivors of childhood cancer, in adult survivors of childhood cancer with elevated pain intensity and pain interference, and in controls.</p>	<p>Study Population: Enrolled in SJLIFE; >18 years of age; ≥10 years from original cancer diagnosis and community comparisons.</p> <p>Inclusion criteria: Participants in SJLIFE who completed a campus visit as of the June 2017 data freeze.</p> <p>Exclusion criteria: Survivors who did not complete SJLIFE questionnaires independently.</p>	02/26/2018		Abstract to be submitted to SIOP	2020	Analyses ongoing

WG update: May 27, 2022										
CCSP CONCEPT/ANCILLARY STUDY REGISTRY Behavioral/Psychosocial Working Group						Working Group Chairs: Tara Brinkman & Rachel Webster				
Principal Investigator/ Senior Mentor	Concept Title	Co-Investigators	Statistician/ Analyst	Objective	Eligibility Criteria	Date CPC Investigator Review	BIMS#/ SJLIFE#	Abstract	Date of Data Freeze	Analysis/ Manuscript Progress
Alberts/ Brinkman	Pain in adolescent survivors of childhood cancer	Papini Krull Ness Tillery Huang Allen Anghelescu Ehrhardt Mulrooney Robison Hudson Armstrong	Sadie	<p><u>Aim 1:</u> To examine the prevalence of pain and pain interference in adolescent survivors of childhood cancer using self- and parent-report.</p> <p><u>Aim 2:</u> To examine treatment, clinical, and demographic factors associated with pain and pain interference in adolescent survivors of childhood cancer.</p> <p><u>Aim 3:</u> To examine associations between chronic health conditions and pain/pain interference among adolescent survivors of childhood cancer.</p> <p><u>Aim 4:</u> To examine associations between pain/pain interference and functional outcomes (i.e., psychological symptoms [anxiety, depression, cancer-related worry], sleep, peer relations, neurocognitive function, physical performance status) among adolescent survivors of childhood cancer.</p> <p><u>Aim 5:</u> To examine associations between pain/pain interference and health behaviors (alcohol use, tobacco use, marijuana use, physical activity) in adolescent survivors of childhood cancer.</p>	<ul style="list-style-type: none"> - ≥5 years from original cancer diagnosis - 11-17 years of age at time of SJLIFE visit - Completed a campus visit as of the June 2020 data freeze 	12/20			2020	In queue for analysis
Allen/Willard	Post-traumatic Stress in Adult Survivors of Childhood Cancer	Phipps Klosky Li Robison Hudson	Li, C Srivastava	<p>To determine factors – cancer-related, demographic, and psychological – associated with stress-related symptoms in adult survivors of childhood cancer.</p> <p><i>Exploratory Aim:</i> To identify the proportion of survivors who spontaneously identify cancer (or a related event) as their most stressful event.</p>	All survivors eligible for SJLIFE.	10/13/2014	2014PS05 5055		10/31/14	J Cancer Surviv. 2018 Apr;12(2):216-223

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Asfar/ Brinkman	Craving to Quit smoking cessation intervention of adult survivors of childhood cancer	Hung Tillery-Webster Ness Hudson	TBD	1) the feasibility and acceptability of the mindfulness app vs. group in-person mindfulness-based smoking cessation or usual care/control (UC) intervention. 2) the preliminary effect of mindfulness on perceived stress and depressive symptoms among young cancer survivors seeking tobacco treatment - 3) perceived distress as an underlying mechanism for the effects of mindfulness on cessation.	<ul style="list-style-type: none"> - 18-40 years old - diagnosed with cancer (any histologic subtype of cancer is qualified for entry into this study), - have smoked ≥ 5 cigarettes/day in the past year - interested in making a quit attempt in the next 30 days own a smartphone read/speak English, -are not pregnant or planning to be pregnant in the next 6 months	TBD				
Bjornard/Ness	Sexual Dysfunction in Women Surviving Childhood Cancer	Chemaitilly Klosky Hudson Robison Brinkman Green Willard Jacola Krasin	Srivastava Huang	<ul style="list-style-type: none"> - To estimate the prevalence of sexual dysfunction among women surviving childhood cancer. - To compare sociodemographic, medical and treatment, hormonal, health-related quality of life, and psychological factors among adult women surviving childhood cancer with/without sexual dysfunction. - To evaluate associations between sociodemographic, medical and treatment, hormonal, health-related quality of life and psychological factors and psychosexual dysfunction among women surviving childhood cancer. 	Female SJLIFE participants with IQ ≥ 70 , had an on campus visit, and completed the Women's Health Questionnaire.	11/14/2016	2016PS04		10/31/14	J Sex Medicine. 2020; 17(10): 1981-1994

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Boatner/ Webster/ Brinkman	Implementing a standardized substance use measure and brief-linked intervention into routine psychosocial care with adult survivors of childhood cancer	Hudson Ness Lavecchia Srivastava	TBD	1) To assess the feasibility of implementing a standardized assessment to screen for substance abuse and deliver a brief-linked intervention in adult survivors of childhood cancer - 2) To examine the effectiveness of delivering a brief intervention for reducing substance use behaviors in adult survivors	- Enrolled in SJLIFE - ≥18 years of age - English language proficient	<u>TBD</u>				
Brennan/ Brinkman	What is an Eye Worth: The Medical and Psychosocial Impact of Enucleation vs. Ocular Salvage in Adult Survivors of Retinoblastoma	Merchant Qaddoumi Wilson Hoehn Mulrooney Phipps Robison Hudson		- To examine the cumulative burden of medical late effects in survivors treated with enucleation vs. ocular salvage. - To examine the psychosocial impact of enucleation vs. ocular salvage.	Adult survivors of retinoblastoma enrolled in SJLIFE.	11/13/2017	2017PS04		2017	Updating analysis with current data freeze
Brinkman	Social Functioning in Adult Survivors of Childhood Brain Tumors	Gurney Armstrong Gajjar Liu Robison Hudson Krull	Liu Srivastava	- To examine social cognition and functioning in long-term adult survivors of childhood brain tumors. - To obtain pilot data to determine the need for larger-scale studies of social functioning and to identify targets for future intervention.	SJLIFE participants with brain tumor diagnosis with 1) No cranial radiation therapy 2) Infratentorial brain tumor and treatment with cranial radiation therapy or 3) Supratentorial brain tumor and treatment with cranial radiation therapy	<u>05/23/2011</u>	2011PS01	Oral presentation at INS Oral presentation at ISPNO		Pilot data used for St. Baldrick's Foundation grant and development of FACES protocol (see below). No manuscript planned.

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Brinkman	Social Cognition and Brain Integrity in Survivors of Pediatric Medulloblastoma (FACES)	Sabin Ogg Reddick Glass Scoggins Krull Gajjar Armstrong Banerjee Robison Hudson	Srivastava	<ul style="list-style-type: none"> - To evaluate social cognition in adolescent and young adult survivors of pediatric medulloblastoma. - To examine indices of brain integrity and function and their association with facial affect recognition in survivors of pediatric medulloblastoma. 	60 MB survivors; >3 years at diagnosis; >5 years post-dx; treated with CSI. 30 aged 12-18 with age, sex, race matched healthy controls 30 aged 19-35 with age, sex, race matched healthy controls.	07/27/2015		ISPNO 2021		Analysis ongoing.
Brinkman	Scarring/Disfigurement, Body Image and Psychological Distress in Adult Survivors of Childhood Cancer	Ojha Kimberg Klosky Srivastava Krull Robison Hudson	Li, C. Srivastava	<ul style="list-style-type: none"> - To assess the frequency of psychological distress, suicide ideation, and post-traumatic stress, negative perceptions of body image, and scarring and disfigurement among adult survivors of childhood cancer enrolled in SJLIFE. - To assess the total, direct, and indirect effects (through body image) on psychological distress, including posttraumatic stress symptoms. - To assess the total, direct, and indirect effects (through body image) on suicide ideation. 	SJLIFE participants who completed the Brief Symptom Inventory-18 and/or PTSD Checklist (PCL) independently.	<u>05/19/2014</u>	2014PS01	APOS oral presentation	10/31/14	Psychooncology. 2018; 27(1):216-222.

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Brinkman	Functional Independence and Health Status Among Adult Survivors of Childhood Central Nervous System Tumors	Ness Krull Chemaitilly Khan Gajjar Klosky Krasin Merchant Boop Klimo Robison Hudson Armstrong	Li, Z. Srivastava	<ul style="list-style-type: none"> - To identify classes of functional independence using multiple indicators (i.e. independent living, employment, marital status, driver's license, assistance with personal care/routine needs) among adult survivors of childhood central nervous system tumors. - To assess whether survivors with deficits in strength, flexibility, balance, muscular endurance, mobility, aerobic functioning, and adaptive physical functioning (e.g., writing, eating, dressing, climbing stairs) have greater risk of non-independence compared to survivors without such deficits. - To assess whether non-independent survivors have greater risk of psychological distress, diminished quality of life, perceived negative impact of cancer, and substance use compared to survivors who are functionally independent. 	<ul style="list-style-type: none"> - Diagnosis of CNS tumor treated at SJCRH - Survived >10 years from diagnosis - >18 years of age at time of evaluation 	04/06/2015	2015PS05	<p>Poster discussion ASCO</p> <p>Oral presentation ISPNO</p>	06/15	JCO. 2018; 35(27):2762-2769.
Papini/Krull/Brinkman	Neurocognitive Function as a Predictor of Health Behavior in Adult Survivors of Childhood Cancer	Klosky Robison Ness Tillery Webster Hudson Krull	Sadie	<ul style="list-style-type: none"> - To examine the association between neurocognitive function and risky health behaviors among adult survivors of childhood cancer. 	SJLIFE survivors who completed neurocognitive evaluations and SJLIFE questionnaires.	04/23/2012	2012NS3 BIMS 4584	Oral presentation INS 2016.		Updating analysis with current freeze.

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Brinkman/ Krull	eHealth intervention for late effects of childhood cancer			<p>Aim 1: To examine the efficacy of an eHealth intervention for improving symptoms of insomnia of adult survivors of childhood cancer.</p> <p>Aim 2: To examine the impact of an eHealth intervention for insomnia on the clinical severity of insomnia symptoms in adult survivors of childhood cancer.</p> <p>Aim 3: To determine whether treatment of insomnia symptoms will improve neurocognitive function in adult survivors of childhood cancer with both insomnia and neurocognitive impairment.</p> <p>Aim 4: To explore the mediating effects of improved neurocognitive function, emotional distress, and cardiovascular health on the association between insomnia symptoms and quality of life.</p> -	<p>Inclusion:</p> <ul style="list-style-type: none">Enrolled in CCSS18 to 65 years of ageClinically significant insomniaNeurocognitive impairmentRegular access to internetAbility to read and speak English <p>Exclusion:</p> <ul style="list-style-type: none">History of brain tumorIrregular sleep schedulePregnant/breastfeedingBehavioral treatment for insomnia past 12 monthsDx'd schizophrenia or psychotic d/oAlcohol or substance abuseConcurrent sleep d/o					Data collection ongoing
Brinkman/ Ness	Pain and Physiologic Frailty in Adult Survivors of Childhood Cancer	Ehrhardt Delaney Partin Krull, M Srivastava Armstrong Robison Hudson	Li, Z	<p>- Examine cross sectional associations between pain and frailty</p> <p>- Examine longitudinal associations between pain and frailty progression</p> <p>- Examine the mediating role of health behaviors on associations between pain and frailty</p>	<p>- Enrolled on FRAILTY protocol</p>			Oral presentation SIOP 2021		Analyses ongoing
Brinkman/ Ness	Psychosocial Health, Functional Independence and Physiologic Frailty in Adult Survivors of Childhood Cancer	Delaney Tillery Partin Krull, M Srivastava Armstrong Robison Hudson	Li, Z	<p>- Examine cross sectional associations between psychosocial health and frailty</p> <p>- Examine associations between functional independence and frailty</p>	Enrolled on FRAILTY protocol					Analyses planned

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Chemaitilly/ Klosky	Sexual Dysfunction in Men Surviving Childhood Cancer	Schover Gleason Brinkman Willard Jacola Hudson Robison Ness Sklar Srivastava	Srivastava	<ul style="list-style-type: none"> - To describe the prevalence of male erectile and sexual dysfunction in survivors in the SJLIFE cohort. - To develop multivariable models based on the results of the univariable analyses in Aim 1 to determine which factors independently increase the risk of male erectile and sexual dysfunction in SJLIFE participants. - To assess the prevalence of psychological distress and physical fitness impairments in patients with male erectile and sexual dysfunction. - To develop multivariable models based on the results of the univariable analyses in Aim 3 to determine which psychological distress and physical impairment factors are independently significantly associated with male erectile and sexual dysfunction. 	SJLIFE participants who independently completed the Men's Health Questionnaire.	10/03/2016	2016PS03	2018 ASCO Survivorship Conference		JAMA Oncol. 2018 Nov 1;4(11):1613-1616
Crom/ Brinkman	Childhood Cancer Survivors Workplace Experiences (SJLA2)	Hudson Hebl Martinez Ness Robison	Ness	To investigate the workplace experiences of childhood cancer survivors.	First 500 participants in SJLIFE with history of current or previous employment.	<u>01/27/2009</u> <u>02/24/2009</u>	2009PS01			J Cancer Surviv. 2018; 12(4):469-478.
Fernandez-Pineda	Long-Term Functional Outcomes and Quality of Life in Adult Survivors of Childhood Musculoskeletal Sarcomas of the Extremities	Hudson Pappo Bishop Klosky Brinkman Srivastava Neel Rao Davidoff Krull Robison Ness		To compare physical performance, QOL, and social attainment outcomes in adult survivors of childhood musculoskeletal sarcomas of the extremities to a group of adults not treated for childhood cancer frequency matched on age-, sex- and race.	SJLIFE participants diagnosed with childhood musculoskeletal sarcomas of the extremities who have completed the protocol's functional assessment.	<u>09/08/2014</u>	2014PS04		10/31/14	J Cancer Surviv. 2017;11(1):1-12.

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Hoehn/ Brinkman	Ocular Complications among Adult Survivors of Childhood Cancer: A report from the St. Jude Lifetime Cohort Study	Wilson, M. Pappo Gajjar Pui Brennan Krasin Robison Ness Brinkman Hudson	Wang Srivastava	To estimate the prevalence of long-term ocular complications among adult survivors of childhood cancer; assess associations between treatment exposures and ocular outcomes in these long-term survivors; and examine potential associations between ocular complications and social and physical functioning in adult survivors.	SJLIFE participants at-risk for ocular complications because of disease or treatment exposure - Treatment with busulfan, dexamethasone, prednisone, radiation (cranial, orbital/eye, total body, nasopharyngeal, Waldeyer's ring, ear/infratentorial), enucleation, or hematopoietic stem cell transplantation - Diagnosis of optic pathway glioma or retinoblastoma	<u>01/12/2015</u>	2015PS01	Presented at American Academy of Ophthalmology	2017	Manuscript being drafted

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Hsiu-Ju Yen/Huang	Patient-Reported Outcomes in Long-term Adult Survivors of Childhood Hematologic Malignancy Treated with Hematopoietic Stem Cell Transplant	Eissa Bhakta Brinkman Krull Phipps Hudson Robison	Srivastava	<ul style="list-style-type: none"> - Compare individual physical and psychological symptoms between the HSCT group, CC group, and CT group, and compare positive cancer impact between the HSCT group and CT group. - Identify socio demographic and transplant-related factors that are associated with physical and psychological symptoms and positive cancer impact in the HSCT group. - Test cumulative prevalence of individual symptoms domains alongside years since HSCT completion by individual symptom domains between the HSCT, CT and CC groups. - Test whether childhood HSCT and CT survivors, respectively, who have chronic conditions experience more impaired physical/psychological symptoms and PTSS as well as less positive cancer impact than HSCT and CT survivors, respectively, who don't have chronic conditions; and compare whether the impact of chronic conditions on PROs between HSCT and CT survivors is in the same magnitude or not. 	<p>Inclusion Criteria</p> <p>HSCT and CT groups:</p> <ul style="list-style-type: none"> - ≥18 years of age; - Diagnosed with a hematologic malignancy (acute lymphoblastic leukemia, acute myeloid leukemia, chronic myeloid leukemia, Hodgkin lymphoma, non-Hodgkin lymphoma, and myelodysplastic syndrome) after January 1st, 1982; <p>CC group:</p> <ul style="list-style-type: none"> - ≥18 years of age; - Non-first degree relatives or friends of St. Jude patients or former patients or SJCRH employees/affiliates who are not SJLIFE study team members, or family members of SJLIFE study team, or supervised by a SJLIFE study team members or any volunteer not associated with St. Jude; - Participant is not currently pregnant or lactating. 	06/10/2016			06/15	Blood. 2020. 135 (21): 1847-1858.

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Huang	Dynamic Randomization Trials to Empower Adaptive Management of Symptoms (DREAMS) in Adult Childhood Cancer Survivors: A Pilot Study	Krull Ness Brinkman Robison Hudson	Srivastava	<ul style="list-style-type: none"> - To assess feasibility of recruitment, participant adherence, and data monitoring and collection for the interventional strategy. - To examine the switch patterns between different interventional strategies per tailoring variables (i.e., a response to the outcome progress) at different time points. - To obtain estimates of potential efficacy of different interventions on improving individual symptoms, functional status, and other outcomes over time, in order to power a large clinical trial. 	<ul style="list-style-type: none"> - Currently enrolled in SJLIFE Cohort Study; - ≥18 years old; - ≥10 years from initial cancer diagnosis; - Mild to moderate of psychological distress and either pain or fatigue symptoms in the past month 	<u>04/27/2015</u>	2015PS06			On hold.
Huang	Relationship Between Treatment-related Chronic Conditions, Symptom Presence, and Quality of Life in Adult Survivors of Childhood Cancer: A Health Utility Approach	Horan Bhakta Brinkman Ness Krull Robison Hudson	Srivastava	<ul style="list-style-type: none"> - Compare health utilities between the adult survivors of childhood cancer and the general population derived from the CDC's Medical Expenditure Panel Survey (MEPS) [25] and University of Wisconsin-Madison's US National Health Measurement Study (NHMS) [26] using the SF-6D utility index. - Determine the relationship between cancer treatment exposures and health utilities using the SF-6D utility index. - Evaluate the relationship between cancer treatment-related toxicities (e.g., overall and specific chronic conditions) and health utilities using the SF-6D utility index. - Determine the association between symptom presence and health utilities using the SF-6D utility index. 	Survivor eligibility in SJLIFE included individuals aged ≥18 years old at enrollment in SJLIFE, cancer treatment at St. Jude Children's Research Hospital (SJCRH), and had survived 10 or more years since original cancer diagnosis.	<u>05/18/2015</u>	2015PS07	SIOP 2022		Analysis ongoing.

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Huang	Financial Hardship and Health Outcomes in Adult Survivors of Childhood Cancer: Determinants and Impacts	Brinkman Klosky Baker Ness Krull Srivastava Hudson Robison		<ul style="list-style-type: none"> - To generate financial hardship indicators based on items of SJLIFE questionnaire and compare financial hardship between cancer survivors and community controls. - To test the extent to which treatment and human capital/economic factors affect financial hardship in adult survivors of childhood cancer. The main human/economic factors include education attainment, employment status, and family income. - To test the extent to which financial hardship affects various outcomes in adult survivors of childhood cancer. 	Survivor eligibility in SJLIFE included individuals: 1) aged ≥18 years old at enrollment in SJLIFE, 2) cancer treatment at St. Jude Children's Research Hospital (SJCRH), and 3) had survived 10 or more years since original cancer diagnosis. Exclusion criteria will include survivors who decline any level of study participation and proxy-reports. Additional, community controls recruited from SJLIFE will be used to compare the financial hardship status.	06/13/2016	2016PS02	NCI/CDC/ACS Biennial Cancer Survivorship Research Conference (oral)	06/15	JNCI. 2018; 111(2):189-200.

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Huang	Validation of PROMIS Measures in Pediatric Cancer Survivors (SJCRH) The Child-Centered Outcomes in Practice and Research (COPR) Center of Excellence: Strengthening the Clinical Validity Evidence Base for PROMIS Measures in Chronically Ill Children (CHOP)	Baker Brinkman Ness Krull Mandrell Hudson Robison	Srivastava	<ul style="list-style-type: none"> - Assess the content validity of the PROMIS Pediatric measures in childhood cancer survivors. - Establish clinically meaningful classifications for the PROMIS Pediatric measures. - Estimate minimally important differences of the PROMIS Pediatric measures. - Evaluate the longitudinal construct validity of the PROMIS Pediatric measures by accounting for past anticancer therapies, clinical markers of current disease activity, and sociodemographic characteristic. 	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> - Age at assessment: 8-15.9 years (survivors) - ≥ 18 years (parents/caregivers); - Pediatric cancer diagnoses; - ≥ 2 years off therapy & ≥ 5 years since diagnosis; <p>Exclusion criteria:</p> <ul style="list-style-type: none"> - Receiving bone marrow transplant; - Severe neurocognitive impairment that requires parents/proxies to complete the survey; - Inability to read and speak English; - Inability to use an iPad/computer to answer the survey. 	01/04/2016		<p>1st ms: 2007 MASCC annual meeting (poster & presentation)</p> <p>2019 ISOQOL (Oral)</p> <p>2020 ISOQOL (Oral – Jin-ah Sim: New Investigator award winner)</p> <p>2021 ISOQOL (Oral – Zhaohua Lu: New Investigator Award finalist)</p>		<p>NIAMS/NIH U19 funded.</p> <p>Quality of Life Research. 2018; 27(7): 1877-1884.</p> <p>BMJ Open. 2020 May 17;10(5):e032414.</p> <p>(NLP/ML 1) – JMIR 2021 (https://pubmed.ncbi.nlm.nih.gov/34730546/).</p> <p>(NLP/ML 2) – manuscript drafted</p> <p>SDOH and PROs study - manuscript drafted</p> <p>NLP/ML 3 (clinical validity) – analysis ongoing.</p> <p>(family influence, parenting behavior/Rachel T.) – analysis ongoing</p>

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Huang	Developing a Patient-Reported Outcome Version of the CTCAE for Survivors of Childhood Cancer (PRO-CTCAE-SCC)	Baker Ness Krull Basch Gibson Armstrong Hudson Robison	Srivastava	<ul style="list-style-type: none"> - Conduct item selection process for the PRO-CTCAE-SCC by eliciting symptom content critical to adult survivors of childhood cancer, and creating new items. - Validate the PRO-CTCAE-SCC using objective clinical parameters and psychometric methodology, and compare the performance to legacy symptom scales. - Develop tailored versions of the PRO-CTCAE-SCC (core and target scales) for survivors of different diagnoses who were exposed to different cancer therapies and establish meaningful cut-points and minimally important differences (MIDs) for clinical decision-making. 	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> - ≥16 years of age at time of this study; - ≥5 years from initial diagnosis of pediatric cancer/malignancy (CCSS/SJLIFE survivors) and currently not receiving cancer therapies <p>Exclusion criteria:</p> <ul style="list-style-type: none"> - Known severe neurocognitive impairment, which requires proxies/parents to complete the survey; - Not able to communicate in English; - Not able to use and/or access internet or computer/tablet 	09/28/2015		2021 ISOQOL (Tegan Reeves - Oral)		<p>R01 funded. Data collection ongoing.</p> <p>First manuscript (content validity 1) – analysis completed, manuscript under development;</p> <p>Second manuscript (content validity 2) – analysis ongoing, abstract planning;</p> <p>Third manuscript (SDOH and late effects – a scoping review: a special invitation by EiC to focus on this topic) – Frontiers in Public Health 2021 (In Press)</p>

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Huang	Impact of Social Network on Health Outcomes: A Comparison Between AYA Survivors and Age/Sex/Race-matched Controls	Huang Brinkman Hudson Robison	Srivastava	<ul style="list-style-type: none"> - Characterize and compare social network structure in young adult survivors of childhood cancer (YASCC) and the matched controls. - Compare effects of social networks, social supports and coping skills on physical and mental HRQOL in YASCC and the controls. - Assess the extent to which demographic and clinical factors (time since cancer diagnosis, cancer diagnosis, and cancer treatment) contribute to different levels of social networks, social supports, and coping skills in YASCC. 	Inclusion criteria: <ul style="list-style-type: none"> - Being diagnosed with leukemia, CNS malignancies (all histologies), Hodgkin's disease, non-Hodgkin's lymphoma, kidney cancer, neuroblastoma, soft tissue sarcoma, or malignant bone tumor; - Age <18 years at the time of diagnosis; - Survival of ≥5 years from the time of diagnosis; - Aged between 18 and 30 years of age at the time of study. 	Non-SJ data		1st ms and 2nd ms: 2017 Int'l Meeting on Long-Term Complications (posters) 2nd ms: ISOQOL annual meeting, Oct 2017 (oral)		Cancer. 2018; 124(10):2220-2227. Pragya Poudel (post-doc) - JCO Clinical Cancer Informatics 2021 (https://pubmed.ncbi.nlm.nih.gov/34415790/)
Huang	Opioid and Marijuana Use in Adult Survivors of Childhood Cancer: A Report from St. Jude Lifetime Cohort Study	Huang Angelescu Ehrhardt Alberts Buckley Allen Brinkman Greene Srivastava Klosky Robison Hudson	Li	Aim 1: To estimate prevalence of opioid use, marijuana use, and dual-use. Aim 2: To characterize opioid by short-acting and long-acting drugs among opioid users. Aim 3: To test associations of pain interference with opioid use, marijuana use, and dual-use.	Inclusion criteria: <ul style="list-style-type: none"> - Diagnosed with childhood cancer before 18 years of age - Age at the time of survey completion ≥ 18 years of age - Completed SJLIFE Home survey and Health Habit survey at baseline - Exclusion criteria: Proxy-reports for Home survey and/or Health Habit survey	No CPC		SIOP 2018		JNCI Cancer Spectrum. 2020; 4(6); pkaa070.

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Huang	Validation of Self-reported Smoking Status by Serum Cotinine in Adult Survivors of Childhood Cancer: A Report from St. Jude Lifetime Cohort study	Klosky Murphy Srivastava Hudson Robison		<ul style="list-style-type: none"> - To validate the misclassification of self-reported smoking status (never, past, and current smokers) using serum cotinine data. - To identify factors (i.e. age at smoking initiation, educational background, income level, social desirability, psychological distress, cancer diagnosis, cancer therapy, chronic conditions, etc.) that may contribute to a misclassification of three respective self-reported smoking statuses (i.e. never, past, and current smokers). - To compare self-reported (never, past, and current) and cotinine-based smoking status with health outcomes and risky lifestyles/behaviors other than smoking. 	<ul style="list-style-type: none"> - ≥ 18 years of age at baseline survey completion; - Have participated in a baseline or follow-up survey; - Have drawn a blood/serum sample with the date near survey completion. 	No CPC		<p>1st ms: 2017 ASCO (poster) and 2017 Int'l Meeting on Long-term Complications (posters)</p> <p>2018 ASCO Survivorship Meeting</p>	2016	Pediatr Blood Cancer. 2018; 65:e27240
Huang/Krull	Symptom Progress and Adverse Health Outcomes in Adult Survivors of Childhood Cancer	Krull Armstrong Hudson Robison Srivastava	Li, C.	<ul style="list-style-type: none"> - To investigate presence of individual symptom domains and symptom clusters in multiple time points spanning 25 years among adult survivors of childhood cancers, and to investigate the survivors' change of symptom clusters over time related to treatment intensity. - To investigate the prognostic value of individual symptom domains and symptom clusters for the development of chronic conditions and all-cause mortality in adult survivors of childhood cancers. 	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> - ≥10 years from initial diagnosis of pediatric cancer/malignancy; - ≥18 years old; - enrolled in the CCSS and SJLIFE studies; - participated in the CCSS 1992 baseline (T1), CCSS 2007 follow-up survey (T2), and SJLIFE (T3). <p>Exclusion criteria:</p> <ul style="list-style-type: none"> - known severe neurocognitive impairment, which requires proxies/parents to complete the symptom survey 	01/12/2015	BIMS 5712	<p>ASCO 2018 ISOQOL 2018 (Invited plenary talk);</p> <p>SIOP 2020 (Oral)</p>	Both CCSS and SJLIFE data	NCI R21 funded. Analysis completed – CHCs, and manuscript is under development (Aim1) Analysis ongoing – mortality (Aim 2)

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Huang/Yasui	Patient-generated health data to predict childhood cancer survivorship outcomes	Ness Sablaue Hudson Armstrong Robison		- Use a mHealth platform to collect and integrate symptoms, activity, and health behavioral data, and develop/validate risk prediction models for future QOL outcomes using these dynamic data -	Inclusion criteria: - ≥18 years old - enrolled on SJLIFE - ≥ 5 years from diagnosis - not receiving cancer directed therapies - access to web-enabled smart phone Exclusion criteria: - known severe neurocognitive impairment - < 3 rd grade reading level or not able to communicate in English - pregnant or plans to become pregnant in next 2 years	No CCSP			Pending data collection	NIH R01 funded; study in development
Huang/Yasui	Assessing the feasibility of remote mindfulness based intervention (RMBI) for childhood cancer survivors: A pilot study	Hudson Robison		- To evaluate feasibility, fidelity, and sustainability of administering a 6-week intervention using UCLA's mindfulness awareness program (MAP) material with 30 childhood cancer survivors through monitoring the status of enrollment, engagement, completion, and the use of MAPs materials - To collect user's experience through 1) brief satisfaction survey, 2) semi-structured interviews, 3) journal entries and research memos - To estimate effect sizes for the change of patient reported outcomes pre and post intervention	Inclusion criteria: - ≥18 years old - enrolled on SJLIFE - <u>at least 2 years off therapy</u> - able to speak and read English - <u>own a compatible smart phone</u> - <u>have internet/wifi accessibility</u> Exclusion criteria: - mindfulness training in past 2 years - estimated IQ less than 80 - unable to speak and read English - unable to access platform that provides intervention	No CCSP			Enrolling participants	Pilot study; in development A manuscript based on meditation study of 2020 national data – analysis ongoing

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Kaye/Baker	Understanding Communication in Healthcare to Achieve Trust (U-CHAT): A Prospective Longitudinal Investigation of Communication between Pediatric Oncologists, Children/Adolescents with High-Risk Cancer, and their Families at the Stressful Times of Disease Relapse or Progression	Baker Levine Mandrell Brinkman Roter	Srivastava	To identify recurrent verbal and nonverbal communication techniques employed by pediatric oncologists (POs) in the delivery of difficult prognostic information to parents of children with cancer (POCCs) through content analysis of audio recorded conversations between POs and parents of children with high-risk cancer at the times of disease reevaluation. <i>Exploratory Aim:</i> To investigate concordance between PO and parent understanding of presented information and overall impression of communication quality.	Inclusion criteria relating to Patients: - Patient's PO is enrolled in this study. - Patient has been diagnosed with one or more of the following diseases: high-risk neuroblastoma, any sarcoma, any carcinoma, desmoplastic small round cell tumor, or incompletely resected or metastatic retinoblastoma, Wilms tumor, or melanoma. - Patient is projected to have ≥ 2 future time points of disease reevaluations, as documented in the electronic medical record (EMR) and/or confirmed by the child's PO. - Patient is being treated for one of the above high-risk diseases with <3 months until end-of-therapy disease evaluation. OR - Patient's disease has relapsed, progressed, or not responded to therapy, as documented in the electronic medical record (EMR) and/or confirmed by the child's PO.	<u>11/16/2015</u>	2016PS01	AAHPM, 2017		Cancer. 2020 126(1): 131-139.

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Kinchen/Wilson	The Influence of Neighborhood Deprivation on Health Behaviors Among Survivors of Childhood Cancer	Brinkman Huang Webster Ness Srivastava Hudson Robison Kevin Krull	TBD	<p>Aim 1: Characterize associations between nSES and health behaviors in adult survivors of childhood cancer.</p> <p>a). To characterize associations between nSES (ADI) and individual SES factors with health behaviors among survivors and</p> <p>b). To test if the association between individual SES and health behaviors is modified by nSES.</p> <p>Aim 2: Characterize associations between nSES, functional independence, and health behaviors.</p> <p>a). To test if functional independence is associated with health behaviors in childhood cancer survivors and</p> <p>b). To determine if nSES modifies the association between functional independence and health behaviors</p>	<ul style="list-style-type: none"> • SJLIFE participants • aged ≥ 18 • ≥ 5 years since diagnosis • attended St. Jude campus during or after 2010. 					

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Lange/Brinkman	Longitudinal changes in functional independence in adult survivors of pediatric brain tumors	Armstrong De Blank Ness Chow Howell Weldon Robison Krull	Leisenring	<p>Aim 1: To identify/confirm latent classes of functional independence in adult survivors of pediatric brain tumors.</p> <p>Aim 2: To identify change in class membership over time.</p> <p>Aim 3: To determine the impact of treatment exposures and chronic conditions associated with changes in class membership over time.</p> <p>Aim 4: To examine the association between declining independence with health-related quality of life and emotional distress.</p> <p>Exploratory Aim: To examine baseline classes of functional independence in the expansion cohort and compare these to baseline classes of functional independence in the original cohort.</p>	<p>Study population: Adult survivors in the original CCSS cohort, diagnosed with a primary brain tumor who completed baseline, FU4, and/or FU 5 (baseline and at least one follow-up survey). Adult survivors in the expansion cohort, diagnosed with a primary brain tumor, who completed a baseline survey.</p> <p>Exclusion criteria: Genetic syndromes associated with cognitive impairment unrelated to primary cancer diagnosis, e.g. Klinefelter or Turner.</p> <p>-</p>					Analysis ongoing
Lehmann/ Klosky	Perceptions of Infertility Risk, Sexual Risk-Taking, and Gonadal Functioning among Adult Survivors of Childhood Cancer: A Report from the St. Jude Lifetime Cohort Study	Chemaitilly Green Kutteh Brinkman Srivastava Robison Hudson		<ul style="list-style-type: none"> - To describe infertility risk perceptions among adult survivors of childhood cancer, and to identify factors associated with these perceptions - To test the associations of perceived infertility risk with relationship status, sexual risk-taking behavior, and psychological distress - To test the congruence of survivors' perceptions of infertility risk vs. biomarkers of gonadal functioning (i.e. hormone levels/ semen analysis) and to test factors associated with this (in)congruence 	<ul style="list-style-type: none"> - Long-term survivors (age 18+) enrolled in SJLIFE - Survivors who have never conceived/sired a pregnancy - Data freeze: June 2016 - Completed Men's/Women's Health Questionnaire (fertility-related questions, sexual risk-taking behaviors); completed parts of the 'Behavior survey' (distress/impact cancer) 	07/13/2017				JCO. 2019 10;37(898-902).

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Lindsey/Yasui	Assessing Racial/Ethnic Disparities in Health Outcomes and Healthcare Utilization Among Long-term Adult Survivors of Childhood Cancer	Hudson Robison Klosky Brinkman Huang Bhakta		- To describe and assess differences in chronic health conditions among survivors in the St. Jude Lifetime Cohort Study (SJLIFE) by race/ethnicity and insurance status.	- To describe and assess differences in chronic health conditions among survivors in the St. Jude Lifetime Cohort Study (SJLIFE) by race/ethnicity and insurance status. - To examine and describe changes in healthcare utilization among survivors in the St. Jude Lifetime Cohort Study (SJLIFE) after the Affordable Care Act (ACA) health insurance mandate was fully implemented by race/ethnicity. - To identify and determine differences associated with the transition to ACT (After Completion of Therapy) among St. Jude survivors by race/ethnicity and insurance status.	07/16/18				J Cancer Surviv. 2021. May 27. Online ahead of print.
Lubas/ Brinkman	Psychosocial morbidity/burden in adult survivors of childhood cancer	Alberts Willard Tillery Reeves Banerjee Krull Hudson Ness Robison	Srivastava	<u>Aim 1:</u> To characterize the patterns and prevalence of psychosocial morbidity in SJLIFE. <u>Aim 2:</u> To examine associations between demographic factors, treatment exposures, and psychosocial morbidity	- SJLIFE - >18 years - >10 years from diagnosis	06/08/2020		Abstract accepted for publication ASCO; Abstract submitted to ISLCCC	2017	Analysis ongoing

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Lubas/ Brinkman	Suicidality among Adult Survivors of Childhood Cancer	Lavecchia Alberts Bhatt Krull Robison Hudson	Mirzaei Srivastava	<p><u>Aim 1:</u> To estimate the prevalence of suicidal ideation, suicidal intent and planning, and suicide attempts in a sample of adult survivors of childhood cancer in SJLIFE compared to a nationally representative sample of adults from the NSDUH survey</p> <p><u>Aim 2:</u> To examine the demographic, treatment-related, physical health-related, and psychological health-related factors that are associated with suicidal ideation among adult survivors of childhood cancer, specifically, examining the contribution of novel risk factors.</p>	<p>Study Population: Enrolled in SJLIFE; ≥ 18 years of age</p> <p>Inclusion Criteria: Participants who completed questions J1-J5 on the SJLIFE questionnaire as of the June 2017 data freeze</p> <p>We will also include the entire SJLIFE cohort for the SMR analysis.</p> <p>Exclusion Criteria: Did not self-complete questionnaire</p>	2019		Abstract submitted to SIOP	2017	Cancer. 2020; 126(24): 5347-5355
Lubas/ Brinkman	Stress/Psychological Distress and Cardiac Late Effects in Adult Survivors of Childhood Cancer	Armstrong Ness Jefferies Krull Robison Hudson	Srivastava	<p><u>Aim 1:</u> To examine the unadjusted and adjusted associations between measures of stress/distress and cardiac late effects among survivors of childhood cancer.</p> <p><u>Aim 2:</u> To examine longitudinal associations between measures of stress/distress and cardiac late effects among survivors of childhood cancer who have completed multiple SJLIFE questionnaires and campus visits.</p>	<p>Study Population: Enrolled in SJLIFE; ≥ 18 years of age</p> <p>Inclusion Criteria: Participants who completed a SJLIFE questionnaire and a campus visit.</p> <p>Exclusion Criteria: Participants who did not self-complete the SJLIFE questionnaire</p>	2019		ASCO poster	2017	CEPB. 2021; 30(2): 286-294

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McDonnell/ Alberts	Cancer-Related Worry and Its Association With Pain, Health Care Utilization, and Health Behaviors in Adult Survivors of Childhood Cancer	Heathcote Gibson Bhakta Ehrhardt Robison Hudson Brinkman	Wang Srivastava	<p><u>Aim 1:</u> To estimate the prevalence of cancer-related worries in adult survivors of childhood cancer.</p> <p><u>Aim 2:</u> To examine treatment, clinical, psychological, and demographic factors associated with cancer-related worries among adult survivors of childhood cancer.</p> <p><u>Aim 3:</u> To examine the relationship between cancer-related worries and self-reported pain intensity and pain interference among adult survivors of childhood cancer.</p> <p><u>Aim 4:</u> To examine the relationship between cancer-related worries and health care utilization among adult survivors of childhood cancer.</p> <p><u>Aim 5:</u> To explore whether relationships exist between cancer-related worry and health behaviors among adult survivors of childhood cancer.</p>	<p>Study Population: Enrolled in SJLIFE; >18 years of age; ≥10 years from original cancer diagnosis.</p> <p>Inclusion criteria: Participants in SJLIFE who completed a campus visit as of the June 2017 data freeze.</p> <p>Exclusion criteria: Survivors who did not complete SJLIFE questionnaires independently.</p>	2019		APOS paper presentation 2020. SIOP al paper presentation, 2021		Cancer. 2021; 127(15): 2743-2751.

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Ness	Impact of Resistance Training and Protein Supplementation on Lean Muscle Mass among Childhood Cancer Survivors	Klosky Lancot Mulrooney Hudson	Ness	- To evaluate the effects of 24-week supervised resistance training with protein supplementation compared to resistance training alone or usual care on changes in lean muscle mass, muscle strength, walking speed, self-reported exhaustion and physical activity levels among childhood cancer survivors. - To evaluate the effects of 24-week supervised resistance training with protein supplementation compared to resistance training alone or usual care on changes in blood pressure, high density lipoprotein, triglycerides, abdominal obesity, fasting glucose, fasting insulin, and C-reactive protein among childhood cancer survivors.		03/16/2014		Presented at ASCO and NASLCCC		Med Sci Sports Exerc. 2020; 52(10): 2069-2077.
Oancea/ Gurney	Emotional Distress among Adult Survivors of Childhood Cancer	Brinkman Ness Krull Smith Robison Hudson	Srivastava	To estimate the prevalence of distress and evaluate the interrelationships among risk factors, including cancer-related late effects.	SJLIFE participants who completed the BSI-18.	<u>09/17/2012</u>				J Cancer Surviv. 2014;8(2):293-303.
Oancea/ Green	The Associations between Cigarette Smoking and Pulmonary Function Impairment in Long-term Survivors of Childhood Cancer	Gurney Ness Ojha Tyc Klosky Robison Hudson	Srivastava	To examine the impact of tobacco use on pulmonary functioning.	SJLIFE survivors whose treatment included pulmonary toxic therapy.	<u>09/17/2012</u>				Cancer Epidemiol Biomarkers Prev. 2014;23(9):1938-43.
Ogg/ Hudson	Does Pediatric Cancer Treatment Affect Survivors' Ability to Breastfeed?	Klosky Ojha Hudson Chemaitilly Carney Robison Cox	Srivastava Wang	To describe breastfeeding outcomes (intention, initiation, duration, and weaning) for mothers who survived childhood cancer, and compare these outcomes with healthy mothers and examine the association between pediatric cancer history and breastfeeding outcomes.	SJLIFE mothers ACT mothers	<u>10/21/2013</u>	2013PS02	Oral presentation 10/2015 at Academy of Breast Feeding Medicine Oral presentation at APON 8/2/2017		J Cancer Surviv. 2020; 14(4):586-599.

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Park/Ehrhardt	Dietary Patterns and Cardiovascular Disease in Childhood Cancer Survivors: St. Jude Lifetime Cohort	Hudson Robison	Mirzaei	<ul style="list-style-type: none"> - To derive and characterize dietary patterns in adult survivors of childhood cancer - To investigate associations between dietary patterns and risk of CVD - To examine the association between dietary patterns and risk of CVD, stratified by underlying CVD risk 	≥5-year survivor SJLIFE campus visit					R03 funded. Analysis ongoing.
Papini/ Brinkman	Web-based screening of psychiatric disorders in adult survivors of childhood cancer	Tillery Srivastava Robison Hudson Ness Krull		<ul style="list-style-type: none"> - To assess the feasibility of conducting web-based screening of psychiatric disorders - The estimate the prevalence of 'cases' of psychiatric disorders 	Inclusion: - ≥18 years of age Exclusion: - not proficient in English - IQ<70	2/21/22				
Shin/Huang	Symptoms, Quality of Life, and Health Behavior Outcomes in Long-term Survivors of Adolescent Cancers: A Report from SJLIFE Cohort Study	Bartlett Dudley Ness Brinkman Klosky Srivastava Hudson Robison Huang		<ul style="list-style-type: none"> - To investigate effects of symptom clusters on HRQOL - To explore the impact of physical symptoms on health behaviors through the moderated mediating effect of psychological variables 	Inclusion criteria: - Diagnosed with any pediatric cancers between (0 to 9.9 years) and (10 to 19.9 years) of age, - 18 years or older at enrollment in SJLIFE, - Survived more than 10 years after cancer diagnosis, - Participated in T1 (baseline) and T2 (a follow-up) surveys, and Participated in campus on-site research or survey-only research.	<u>12/14/2016</u>	2017PS03	2021 ASCO (Poster)	2016	Manuscript drafted and ready to circulate

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Snaman/ Blazen/Baker	Adolescent and Young Adult, Parental, and Health Care Provider Decision Making at End of Life Using Adaptive Conjoint Analysis	Huang Srivastava		To quantify the relative importance of various factors believed to be important to AYA patients with cancer, parents, and HCPs when choosing between treatment options in the hypothetical situation of progressive or refractory disease.	AYA patients (aged 13-30) with cancer who are currently receiving active treatment at St. Jude Children's Research Hospital. Patients will be enrolled after at least 3 months of active treatment. Parents of a patient (<18) who is receiving treatment at St. Jude. If available, parents of young adult patient (≥18) being treated at St. Jude will be invited to participate. HCPs of patients at St. Jude with at least 1 year of experience taking care of AYA oncology patients. HCPs must have an MD or DO degree and be an attending physician or clinical fellow.	<u>03/23/2015</u>	2015PS02			Pediatric Blood and Cancer. 2021; 68 (1): e28755
Stallings-Smith	Outcomes of Chronic Hepatitis C Infection among Adult Survivors of Childhood Cancer	Studaway Krull Brinkman Hudson Ojha		To assess the prevalence of long-term outcomes, including cirrhosis, fibrosis, and mortality, among HCV-seropositive adult survivors of childhood cancer.	≥5-year cancer survivors who were treated at SJCRH, and have chronic HCV infection as determined by second-generation enzyme immunoassay (EIA-2) and recombinant immunoblot assay (RIBA-2) or polymerase chain reaction (PCR).	<u>08/11/2014</u>	2014PS03			J Clin Virol. 2015;71:18-21.
Strauser/ Ness	Childhood Cancer Survivors Workplace Experiences (SJLA2)	Hudson Ness	Huang Srivastava	To estimate the degree of career readiness in young adult cancer survivors.	First 500 participants in SJLIFE with history of current or previous employment	IRB approval: 07/14/2009 <u>01/27/2009</u> <u>02/24/2009</u>	2009PS03			J Cancer Surviv. 2015;9(1):20-9.

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Svensden/ Ness	Organ System Impairments and Fatigue in Adolescent Cancer Survivors	Brinkman Hudson Robison LoRusso	Ness/TBA	To evaluate associations between organ system impairment and fatigue among adolescent survivors of childhood cancer To describe associations between fatigue and adaptive physical function and social function among adolescent survivors of childhood cancer	Adolescent survivors 8-17 years who completed campus visit					Updating analysis with current data freeze.
Tillery/Ness	Parental Factors Linked to Health Protective Behaviors in Young Survivors of Childhood Cancer	Phipps Willard Howard Sharp Krull Huang Hudson Robison	Mirzaei Srivastava	To estimate adherence to HLBs (e.g. diet and PA) among young survivors of pediatric cancer (aged 8-17) based on CDC guidelines. To examine links between parenting practices (e.g., rule setting, parental overprotection), family functioning (e.g., family environment, impact of cancer on the family), HLBs, and functional mobility while controlling for statistically relevant demographic/medical variables.	Caregivers of children aged 8-17 years with a history of cancer, who are enrolled on and completed assessments for SJLIFE and PEPR or SJLIFE and NEULS.	March 2019				Updating analyses.
Tillery/Ness	Health Risk Profiles in Young Survivors of Childhood Cancer	Brinkman Alberts Lanctot Ehrhardt Hudson Robison	Srivastava	1) To empirically derive health behavior profiles of young survivors (<18 years of age) of pediatric cancer. 2) To determine which demographic and medical factors are associated with health behavior profile membership. 3) To examine links between profile membership and health and physical functioning.	Young survivors (<18) of pediatric cancer who are at a minimum 5 years post diagnosis, part of the St. Jude Lifetime cohort study, and have completed study questionnaires	March 2019				Manuscript submitted for publication. Under revisions

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Tillery Webster	Healthy Kids after Cancer: A Health Behavior Change Intervention	Krull Hudson Ness Jacola Sherwood Turcotte Sadak Kelly Eaton Kepper	UMN statistician	1) To evaluate the efficacy of a parent-targeted, telehealth-delivered, health behavior change intervention, the Healthy Kids after Cancer program, on children's health behavior. 2) To determine the impact of the Healthy Kids after Cancer program on child BMI trajectories, cardiometabolic health, and neurobehavioral (i.e., neurocognitive and emotionalbehavioral) function. To examine factors influencing intervention adherence and implementation.	Inclusion: -Primary caregivers of patients with a history of ALL -Patients range in age from 4-12 -Caregiver speaks and reads English. >3 months post treatment completion Exclusion: -Caregivers of patients who received cranial radiation therapy, bone marrow transplant, or who experienced relapse -patients with significant neurologic or psychiatric issues	No CCSP				Not funded; Summer/Fall 2022 resubmission
Tillery Webster/Fue mmeler	Adapting an mHealth vaping cessation intervention for AYA survivors	Amato Graham	Pan	-Examine the prevalence of e-cigarette use among AYA CCS, use behaviors (e.g., timing, frequency), interest in quitting, and quit attempts - Evaluate associations between demographic (e.g., sex, race), cancer-specific (e.g., diagnosis, treatment factors, pain experience), and psychosocial factors linked to survivor e-cigarette use. 3) - Conduct a single-arm trial of TIQ to explore factors influencing uptake of the intervention among AYA CCS	1) 13 to 24 years old at enrollment; 2) followed by SJCRH; 3) in remission and at least 3 months from having completed cancer-directed therapy; 4) English-speaking	TBD				Not funded; Resubmitted to ISC Developmental Awards

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Tillery Webster/ Krull	Symptom profiles and health care utilization in long-term survivors in the childhood cancer survivor study	McGrady Alberts Brinkman Ness Fuemmeler Kunin-Batson Huang Armstrong Howell Green Yasui	Srivastava	<ol style="list-style-type: none"> To identify latent profiles of survivors with similar psychological and physical symptoms (per self-report at Baseline). To compare the pattern of profiles between survivors and siblings. To identify demographic and medical predictors of symptom latent profile for survivors. To evaluate the association between latent profiles at Baseline and healthcare utilization and health behaviors (physical activity, sedentary behavior, smoking, etc.) at Follow-up 2 (original cohort) and Follow-up 5 (expansion cohort) surveys. <u>Hypothesis 4a:</u> Survivors in profiles characterized by elevated levels of both psychological and physical symptom burden will demonstrate decreased physical activity, increased likelihood of smoking behaviors, and increased problematic drinking behaviors. 	All 5-year survivors and siblings who participated in the CCSS Baseline when at least 18 years old, and completed either Follow-up 2 (original) or Follow-up 5 (expansion) surveys.			<p>ASCO 2022 (accepted for online submission), Webster RT, Liu W, McGrady ME, Alberts NM, Brinkman TM, Ness KK, Fuemmeler B, Kunin-Batson AS, Srivastava DK, Huang IC, Armstrong GT, Howell RM, Green DM, Yasui Y, Krull KR. Symptom Profiles and Health Care Utilization in Long-term Survivors of Childhood Cancer Survivor Study (CCSS). American Society of Clinical Oncology Annual Meeting 2022. Chicago, IL.</p> <p>Submitted to SIOP 2022</p> <p>Submitted to ISLCCC 2022</p>		Analysis ongoing

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Principal Investigator/ Senior Mentor	Concept Title	Co-Investigators	Statistician/ Analyst	Objective	Eligibility Criteria	Date CPC Investigator Review	BIMS#/ SJLIFE#	Abstract	Date of Data Freeze	Analysis/ Manuscript Progress
Tonning Olsson/ Brinkman	Prevalence and Functional Consequences of Pain and Comorbid Psychological Distress Symptoms in Adult Survivors of Childhood Cancer	Alberts Krull Ness Klosky Mulrooney Pappo Bishop Angheliescu Robison Hudson Brinkman	Li, C. Liu, W Srivastava	<ul style="list-style-type: none"> - To examine the prevalence of pain and identify latent classes of pain and comorbid psychological distress symptoms in adult survivors of childhood cancer. - To identify cancer-related diagnosis and treatment factors associated with latent classes of pain and comorbid psychological symptoms. - To examine associations between latent classes of pain and comorbid psychological distress symptoms and neurocognition, social attainment, physical performance status, and health related quality of life. 	<ul style="list-style-type: none"> - Enrolled in SJLIFE; - >18 years of age; - >10 years from original cancer diagnosis; - Completed a campus visit as of the June 2016 data freeze. 	04/24/2018	BIMS 5692	Oral presentation at INS 2019.		Cancer. 2021; 127 (10): 1679-1689
Ware/Ness	Exercise-Specific Implicit Associations and Bodily Sensations of Childhood Cancer Survivors	Srivastava Jacola Tillery-Webster Brinkman Hudson Robison Ness	TBD	<ul style="list-style-type: none"> -Assess the feasibility of administering the Single-Category Implicit Association Test (SC-IAT) to young adult survivors of childhood cancer. -Use the SC-IAT to identify affective value -Identify specific body sensations and specific body locations in which young adult survivors experience discomfort during exercise. Identify young adult survivors' thoughts about the meaning or affective value of sensations related to discomfort during exercise. 	Participants enrolled in St. Jude Lifetime Cohort who are between the ages of 18 and 29 at completion of on campus visit, participants with a diagnosis of: CNS tumor, bone tumor, and leukemia or lymphoma.	2/21/22		Ware/Ness		
Willard	Factors Associated with a Positive or Negative Perception of the Impact of Cancer in Adult Survivors of Childhood Cancer	Phipps Brinkman Klosky Robison Hudson	Li, C. Srivastava	To determine factors – cancer-related, demographic, and psychological – associated with either a positive or negative perception of the impact of cancer in adult survivors of childhood cancer.	All survivors eligible for SJLIFE.	<u>10/13/2014</u>	2014PS05		10/31/14	Cancer. 2017; 123(9):1625-1634.

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Willard	Body Image in Adolescent Survivors of Childhood Cancer: Associations with Age at Diagnosis and Perceptions of Disability	Tillery Webster Allen Daneils Vuotto [Biostats] Brinkman Robison Hudson		-Assess the impact of age at diagnosis on the experience of body image in adolescent survivors -Describe the impact of persistent/permanent bodily changes on the experience of body image -Examine associations between perceived disability and body image -Examine associations between body image and distal outcomes, including social functioning, physical activity, and mood	-Enrolled in SJLIFE -13-17 years of age -Completed Body Image Scale	Pending CPC review				
Zhang, FF	Nutritional Status in Adult Survivors of Childhood Cancer	Ojha Hudson Krull Chemaitilly Ness Bhakta		- To evaluate the nutritional status of adult survivors of childhood cancer enrolled in SJLIFE, including the overall diet quality and specific nutrients and food groups. - To evaluate nutritional status in association with survivors' demographic, cancer-related characteristics, behavior risk factors, and selected biomarkers.	SJLIFE participants diagnosed with childhood cancer who completed the food frequency questionnaire (FFQ).	<u>06/23/2014</u>	2014PS02			R03 funded. J Nutr. 2016;146(12):2497-2505

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Zhang, FF	Factors Associated with the Use of Dietary Supplements in Adult Survivors of Childhood Cancer	Chen Ojha Krull Lu Ness Bhakta Huang, IC Robison Hudson		<p>- Describe the prevalence of dietary supplement use in adult survivors of childhood cancer in the SJLIFE cohort, including the use of any vitamin/mineral supplements, multivitamin/mineral (MVM) supplements (defined as supplements containing 3 or more vitamins, either with or without minerals), and single supplements (vitamin A, beta-carotene, vitamin D, vitamin E, vitamin C, folic acid, calcium, selenium, iron, zinc, and fish oil). We will compare the prevalence of supplement use in adult survivors of childhood cancer in SJLIFE to that of a national sample of individuals with and without a history of cancer in the NHANES 1999-2014 by age (ages 18-24.9, 25-29.9, 30-34.9, 35-44.9, and 45-65 years old) and sex groups (male and female).</p> <p>- Evaluate whether supplement use in childhood cancer survivors differs by survivors' (1) demographics (age, gender, race/ethnicity, and education), (2) tumor and treatment characteristics (cancer diagnosis, time from diagnosis, and treatment exposures), (3) behavioral risk factors (diet quality, physical activity, cigarette smoking, alcohol drinking, and body mass index), (4) symptoms, (5) cumulative burden of chronic health conditions (grades 1-5 and grades 3-5 chronic health conditions), and (6) health-related quality of life (physical and mental component summaries score).</p>	SJLIFE participants diagnosed with childhood cancer who completed the Block food frequency questionnaire (FFQ).	01/09/2017	2017PS02			Manuscript draft in progress

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Baedke/Yasui	Genomic analysis of treatment-induced hearing loss among childhood cancer survivors	Bass, Brooke Howell, Hudson Robison, Shelton Srivastava, Wang Zhang, Ness	Sapkota Liu Moon	To identify genetic variants (common and rare) associated with hearing loss in childhood cancer survivors	Genotyped patients and patients included in the WGS cohort (excludes patients with hearing loss prior to cancer treatment)	July 31 st 2017				DISCONTINUED (9/16/2020) Significant hit identified in GWAS, not replicated in WGS dataset
Bhatt/ Mulrooney	WGS study identify genetic factors associated with coronary artery disease (Yasui/Zhang R01)	Yasui Jefferies Armstrong Wilson Robison Hudson	Sapkota	To identify common and rare genetic variants associated with coronary artery disease Construct prediction model for CAD Results from GWAS will be validated in CCSS	WGS sequenced survivors of European ancestry					ON HOLD Collaborating with European groups for replication, sample collection date target May 2020 Dan will follow up with collaborators
Phillips/ Krull	Genome-Wide Association Study of Executive Functions in Adult Survivors of Childhood Leukemia	Liu, Wilson Edelmann, Li Reddick, Srivastava Yang, Robison Hudson	Li, C.	To examine variability in executive dysfunction associated with genetic polymorphisms in adult survivors of childhood ALL.	Adult survivors of childhood ALL enrolled on SJLIFE who completed neurocognitive evaluation and provided DNA samples for GWAS	04/16/2012	BIMS 4604	INS 2017 ICCTF 2018	06/2015	DISCONTINUED Study closed
Brooke/ Chemaitilly	Premature ovarian insufficiency	Yasui Wilson	Li, Z.	To identify SNPs associated with premature menopause among female survivors	Discovery: SJLIFE 805 Validation: CCSS 1644			ASCO 2017		JNCI 2018 Aug 1;110(8):895-904)
Brooke/Krull	Whole genome sequencing study to identify genetic factors affecting treatment-associated risk of neurocognitive outcomes of childhood cancer survivors (SJLIFE and CCSS) (Yasui/Zhang R01)	Brinkman Sapkota Moon Liu Banerjee Bhatia Wilson Zhang Armstrong Hudson Robison Yasui	Brooke	To identify genetic factors (common SNPs and indels) that may affect treatment-associated risk of neurocognitive impairment in four categories (memory, executive function, processing speed, and attention) in SJLIFE participants exposed to at least one neurotoxic treatment	Inclusion 1. European ancestry 2. Neurocognitive evaluation 3. Exposed to either methotrexate, high-dose cytarabine, neurosurgery, CRT, dexamethasone Exclusion 4. Head injury/neurological condition not treatment-related 5. Genetic disorder associated with neurocognitive impairment 6. Non-English speaker 7. Diagnosed prior to 4/1/2012	17/10/23			2016	DISCONTINUED Findings not replicated in second SJLIFE survivor group (all diagnoses) Significant hit for Memory when analyses restricted to ALL- not replicated in SJLIFE expansion cohort Readjusting analyses Discontinue (11/18/2020)

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Evans	Pharmacogenomics of childhood leukemia (Evans R01CA036401)	Goodenough Diouf Yang Sapkota Finch Lu Partin Wogksch Hudson Robison Wang Jeha Ness		To elucidate pharmacogenomics determinants of drug effects in children with ALL	1.SJLIFE is the validation cohort (N=1008) for Evan's findings 2.Perform GWAS using WGS dataset			SIOP 2021		SJLIFE validation successful Manuscript accepted by Leukemia
Green/Sapkota	Azoospermia	Wilson Yasui Roberts Stewart	Sapkota	To identify associations between genetic polymorphisms and azoospermia/oligospermia among SJLIFE participants treated with an alkylating agent included in the cyclophosphamide equivalent dose calculation Candidate gene approach	SJLIFE 5-year survivors with WGS data; Europeans; have completed semen analysis at >=18 years of age; no current use of testosterone; exposed to CED	Not reviewed	NA			Cancer Res. 2020 Sep 1;80(17):3755-3764
Im/Wilson	Genome-Wide Study of BMD in Childhood Cancer Survivors (Wilson FP00003121)	Yasui Hudson Neale Robison	Im	To identify SNPs associated with the incidence of low bone mineral density late effects using a genome-wide association study approach	Discovery: 856 ALL survivors Validation: 1428 survivors of solid tumors and lymphoma	01/24/2011 Paper	NA	ASHG 2016	06/2015	Eur J Hum Genet 2018 Feb;26() 275-286
Im/Yasui	Genetic risk prediction profiles for pulmonary dysfunction outcomes among childhood cancer survivors	Mulrooney Green Stokes Wilson Sapkota Hudson Robison Yasui	Im	Conduct a GWA study with WGS data to identify common and rare variants associated with select pulmonary dysfunction outcomes and related PFT measures among SJLIFE survivors. Assess the extent to which specific sets of genetic predictors improve the discriminatory performance of standard clinical prediction models for pulmonary dysfunction outcomes among survivors.	Inclusion 1. ≥18 years age 2. WGS available 3. European 4. ≥5 year survivor		NA			Under revision at Cancer Research

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Im/Yasui	Transferability of robust genetic findings from genome-wide association studies in childhood cancer survivors	Wilson Sapkota Wang Hudson Robison	IM	To determine whether replication patterns for robust SNP-trait associations identified in non-CCS can be transferred to survivors of childhood cancer				NALSCCC 2019 Talk		Am J Hum Genet. 2020 Oct1 107(4):636-653
Karol	Evaluating effects of ON and glutamate receptor variation on cardiovascular disease in survivors	Ness Wilson Hudson Mulrooney	Lu	Compare rates of arterial vascular disease among survivors of lymphoid malignancies between patients who developed ON and similarly treated controls. Evaluate the risk of arterial vascular disease in survivors carrying glutamate receptor signaling SNPs associated with ON during ALL therapy.			NA			DISCONTINUED No association between tested variants and outcomes of interest after correction for multiple testing – project closed, no publication
Kang	Evaluation of TSIR for internal validation GWAS	Liu Cheng Wilson Neale Yang Ness Robison Hudson Srivastava	Kang	Aim: Simulation studies to assess the utility of the two-step iterative resampling approach		Not reviewed	BIMS 2941	UT-KBRIN Bioinformatics Summit	Not aligned with freeze	J Hum Genet. 2015; 60(12):729-38
McCastlain/ Ness	Identifying the genetic determinants of sarcopenia	Wilson Wang Yasui Cadie Kundu Nolan	Sapkota McCastlain	Determine if mtDNA copy number is associated with sarcopenia Identify SNPs associated with sarcopenia (GWAS) Identify SNPs associated with mtDNA copy number (GWAS)	Sequenced and mtDNA copy number data available Excludes: TRC and MCTC samples		NA		2016	Published on JNCI, 2021
Morton Robison	Genome wide association study identifies susceptibility loci that modify radiation-related risk for breast cancer after childhood cancer	Liu Wilson Neale Ness Srivastava Hudson Robison Lear Kang Yasui Wang Gibson Armstrong	Morton	To perform exploratory GWA analyses for identification of single nucleotide polymorphisms (SNPs) related to the risks of breast carcinoma among long-term survivors of primary childhood cancers participating in the SJLIFE cohort and CCS	SJLIFE participants who had RT and provided DNA samples for GWAS	Not reviewed	NA		06/2015	J Natl Cancer Inst. 2017 Nov 1;109(11)
Ness	Vestibular dysfunction		Sapkota Li, Z. Im	Validate using sequencing data						Hit but no replication –analyses being updated with new data

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Ness/Wang	Shorter leukocyte telomere length reflecting age acceleration is associated with late effects among survivors of childhood cancer	Song Wilson Zhang Hudson Yasui Robison	Li, Z. Howell	To systematically analyze and compare LTL and age dependent LTL attrition rate in survivors an controls, evaluate the association of LTL with treatment and aging related chronic conditions, and the association of LTL with health behaviors among survivors	SJLIFE survivors and community controls of European ancestry	Ancillary Study				Clin Cancer Res. 2020 may 15;26(10):2362-2371
Sapkota	A genome-wide association study of blood pressure in adult survivors of childhood cancer	Robison Hudson Wilson Gibson Jefferies Wang Armstrong Srivastava	Pierzynski/Sapkota		WGS participants or European descent (based on PCA), exclude Wilms tumor	4/22/2019			2017	Published on JACC CardioOncol 2021 Mar;3(1):76-84
Sapkota	Genetic Variants Associated with Therapy-Related Cardiomyopathy among Childhood Cancer Survivors of African Ancestry	Na Qin; Matt Ehrhardt; Zhaoming Wang; Yan Chen; Carmen Wilson; Jeremie Estep; Parul Rai; Jane Hankins; Paul Burridge; John Jefferies; Jinghui Zhang; Melissa Hudson; Les Robison; Greg Armstrong; Daniel Mulrooney; Yutaka Yasui	Sapkota; Qin; Chen	To identify genetic variants associated with cardiomyopathy in African American survivors (2-stage approach)				ASCO 2019		Cancer Res. 2021 May 1;81(9):2556-2565

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Sapkota	A novel locus on 6p21.2 for cancer treatment-induced cardiac dysfunction among childhood cancer survivors (2-stage approach)	Matt Ehrhardt; Na Qin; Zhaoming Wang; Qi Liu; Weiyu Qiu; Kyla Shelton; Ying Shao; Emily Plyler; Heather Mulder; John Easton; Robert Michael; Paul Burridge; Xuexia Wang; Carmen Wilson; John Jefferies; Eric Chow; Kevin Oeffinger; Lindsay Morton; Chunliang Li; Jun Yang; Jinghui Zhang; Smita Bhatia; Dan Mulrooney; Melissa Hudson; Les Robison; Greg Armstrong; Yutaka Yasui								Accepted in principle in JNCI
Sapkota/ Armstrong	Two stage analytic approach to identify risk factors associated with VO2Max and associated phenotypes		Sapkota	1) genetic variants will be tested <u>first</u> for their associations with VO2 max and 2) selected variants from the above step will be tested for associations with the associated phenotypes (eg grip strength)						On hold – considering discontinuing Significant hit could not be replicated In SJLIFE
Sapkota/Yasui/Bhatia	Genome-wide association analysis of survivors of childhood cancers identifies a risk locus in <i>HTR2A</i> for subsequent BCC: A report from the CCSS and the SJLIFE cohort	Ehrhardt Wilson Wang Shelton Qi Zhang Hudson Armstrong Chanock Morton Bhatia	Sapkota	To perform GWA analysis of BCC in the CCSS cohort to identify genetic factors associated with BCC and evaluated top SNP associations in an independent cohort of long-term childhood cancer survivors from SJLIFE	CCSS (Discovery)- 5-year survivors; have GWAS data; Europeans; no BMT SJLIFE (Replication) – 10 year survivors; have GWAS data; European	Not reviewed	NA			J invest Dermatology. 2019 Sep;139(9);2042-2045.e8

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Sapkota/Krull	Stroke	Cheung Tinkle Khan Wilson Srivastava Yasui Brinkman Armstrong Hudson Robison	Sapkota	To identify genetic variants associated with stroke risk (GWAS and rare variant analysis) Findings from GWAS will be replicated in				Poster AACR 2019 – selected for press briefing	7/16/16	Clin Cancer Res 2019 Nov;25(22):6700-6708
Wang/Wilson	Genetic risk for subsequent neoplasms among long-term survivors of childhood cancer	Easton Thrasher Mulder Yasui Nichols Kesserwan Zhang Robison Ehrhardt Hudson	Liu	Assess the contribution of mutations within 156 cancer predisposition genes to subsequent neoplasm risk	3006 cancer survivors whose samples underwent WGS	Not reviewed	NA	AACR 2017	Not aligned with freeze	JCO 2018; Jul 10; 36(20): 2078-2087
Wang	Association of polygenic risk score with subsequent breast cancer in survivors	Wilson Zhang Robison Ehrhardt Hudson Yasui	Liu	To assess the contribution of low risk common variants to the development of subsequent breast cancer	1140 female survivors (European descent) whose samples underwent WGS	Not reviewed	NA	AACR 2018	Not aligned with freeze	Clin Cancer Res DOI: 10.1158/1078-0432.CCR-18-1775
Wang	Germline Mutations in BRCA2 predispose to NHL	Wang, Chang, Wilson, Kesserwan, Gibson, Li, Easton, Mulder, Wu, Edmonson, Downing, Nichols, Bhatia, Armstrong, Hudson, Zhang, Yasui, Robison		To investigate <i>BRCA2</i> as a potential predisposition gene for pediatric/adolescent lymphoma		Not reviewed (Working group or CPC)		AACR 2019 Poster Discussion		JAMA Oncology 2019 Sep 1;5(9):1362-1364
Wang/Ness	Epigenetic Age Acceleration and Chronic Health Conditions among Adult Survivors of Childhood Cancer	Qin, Li, Song, Wilson, Easton, Mulder, Plyler, Neale, Walker, Zhou, Pan, Hudson, Yasui, Robison, Zhang, Ness, Wang	Li	We aimed to investigate epigenetic age acceleration (EAA) in survivors and evaluate associations between EAA, treatment exposures, health behaviors, and chronic health conditions (CHCs)	Genome-wide methylation data were generated with Infinium EPIC BeadChip on blood-derived DNA from 2139 survivors and 282 frequency matched controls from the St. Jude Lifetime Cohort Study.	Not reviewed		AACR 2020 poster		JNCI 2021 May 4;113(5):597-605

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Wang/Ness	Epigenetic age acceleration among adolescent survivors of childhood cancer	Hudson Robison	Dong	Aim 1: Augment existing methylation data to allow for more complete (earlier) examination of the trajectory of aging among adolescent survivors of childhood cancer Aim 2: Evaluate prospective contributions of EAA to the risk of early onset chronic diseases among adolescent survivors of childhood cancer	Adolescent: 10-18y Young Adult: >=18y and <35 Adult: >=35	SJLIFE U01 Supplement				Under review at XX
Wang/Yasui	Polygenic risk of subsequent thyroid cancer after childhood cancer	Song, Liu, Wilson Sapkota, Gibson Morton, Chanock Neglia, Arnold Rusch, Mulder Easton, Zhang Downing, Bhatia Armstrong Chemaitilly, Hudson, Robison	Liu	We aimed to evaluate the polygenic contributions to risk of STC and potential utility in improving risk prediction	St. Jude Lifetime Cohort (SJLIFE, N=2,370) was used for discovery and Childhood Cancer Survivors Study (CCSS, N=6,416) was used for replication.	Not reviewed		ASCO 2019 Poster		Accepted in CEBP
Wang	Persistent Variations of Blood DNA Methylation Associated with Treatment Exposures and Risk for Cardiometabolic Outcomes among Long-term Survivors of Childhood Cancer: A Report from the St. Jude Lifetime Cohort	Song, Hsu, Pan, Zheng, Hou, Sim, Li, Mulder, Easton, Walker, Neale, Wilson, Ness, Krull, Srivastava, Yasui, Zhang, Hudson, Robison, Huang	Song, Hsu, Li	To elucidate the pathophysiology and a possible causal pathway from treatment exposures to cardiometabolic conditions, we conducted epigenome-wide association studies (EWAS) to identify DNA methylation sites associated with cancer treatment exposures and examined whether treatment-associated DNAm sites mediate associations between specific treatments and cardiometabolic conditions.		V foundation grant: Wang/Huang				Genome Med. 2021 Apr 6;13(1):53
Wang/Strathdee (UK)	Cancer treatment associated DNAm and risk of chronic health conditions in SJLIFE	Ness Hudson Robison	Dong	To replicate cancer treatment associated DNAm sites in SJLIFE and evaluate association with CHCs	SJLIFE survivors with WGS and DNAm data					Analysis ongoing
Wang/Huang	Social epigenetic pathways and disparities of adverse health outcomes in adult survivors of childhood cancer	Song, Sim, Li, Srivastava, Yasui, Hudson, Robison, Huang, Wang	Song, Li	Evaluate the association between DNAm and SES factors, Evaluate the mediation of SES-associated DNAm sites for association between SES and CHC risk		V foundation grant: Wang/Huang		AACR 2021		Accepted in Epigenetics Under review at Cancer Communications

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Wang	Germline P/LP variants in DNA repair genes and cardiometabolic conditions risk (R01 resubmitted)	Jefferies Armstrong Yasui Ness Hudson Robison	Song	To evaluate the association between carrier status of DNA repair gene mutations and risk of cardiometabolic conditions						Analysis using SJLIFE is ongoing
Wang	HLA alleles and Hodgkin lymphoma risk	Ness Robison Hudson	Chen, Song	To identify HLA alleles associated with adolescent HL risk	SJLIFE survivors and community controls					Manuscript under review at JAMA Network Open
Wang	Dyslipidemia EWAS	Huang Ness Robison Hudson	Dong	To search for DNAm sites that are associated with dyslipidemia risk				AACR 2021		Reanalysis using blood lipids Manuscript under development
Wang	GWAS of epigenetic age acceleration	Ness Robison Hudson	Dong, Song	To identify the genetic associations with EAA based on four different epigenetic clocks	Survivors with both WGS and DNAm data			ASHG 2021		Accepted by Genome Medicine
Wang	Epigenetic age acceleration in survivors of African ancestry	Huang Ness Srivastava Robison Hudson	Dong	To evaluate racial disparity in EAA between survivors of African ancestry and European ancestry						Waiting for additional DNAm data
Wang	GWAS of Ewing Sarcoma	Hudson Ness Robison	Wang	To identify genetic variants associated with risk of Ewing Sarcoma						Results sent to NCI for further meta-analysis
Williams AM	Aging-related Biomarkers of Neurocognitive Function in Childhood Cancer Survivors	Ness Wang Dong Liu Phillips Kundu Banerjee Sabin Yasui Robison Hudson Ehrhardt Krull	Srivastava Williams	To describe the association between telomere length, epigenetic age acceleration, and immune cell composition with neurocognitive functioning in SJLIFE. To describe the longitudinal association between biomarkers and neurocognitive function in HL survivors.	SJLIFE survivors	April, 2021				Analysis under way
Wilson/ Armstrong/ Jefferies	Genome-Wide Study of Late Effects of Therapy in Childhood Cancer Survivors (FP00003121) (Cardiomyopathy)	Ness Hudson Robison	Yasui	To identify genetic variants associated with left ventricular dysfunction and cardiac structure abnormalities among survivors of childhood cancer		01/24/2011 Paper			Data pending	Waiting for updated phenotype dataset – redefine outcome variable list. Phenotype related paper published

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Wilson/Ness	Obesity (BMI)	Liu Yang Kang Ojha Neale Srivastava Gurney Hudson Robison	Liu	To estimate prevalence of obesity among CCS, and identify clinical and treatment related risks for obesity Conduct exploratory analysis to investigate genetic factors associated with obesity		Not reviewed at CPC	BIMS 4481	AACR 2013	Not aligned with freeze	Cancer. 2015; 121(13):2262-70
Wilson	Prevalence of mutations in cancer predisposition genes among adult survivors of childhood cancer in the US	Wang Ehrhardt Yasui Robison Hudson Zhang	Qi Liu	To estimate the absolute number of childhood cancer survivors in the US population who carry a pathogenic or likely pathogenic mutation in a cancer predisposition gene using data from SEER and SJLIFE	WGS participants	Not review (working group of CPC)	NA		Not aligned with freeze	PBC 2020 Feb;67(2):e28047
Wilson	Genetic risk, adherence to a healthy lifestyle and Metabolic syndrome (dyslipidemia, obesity, hypertension, insulin insensitivity) among survivors of childhood cancer	Ness Yasui Sapkota Armstrong Wang Hudson Robison	Pending	Aim 1: To test the contributions of established genetic and lifestyle risk factors on the risk of developing components of the MetSyn among survivors. Aim 2: To perform GWAS using WGS data to identify common and rare variants associated with components of the MetSyn among cancer survivors. Aim 3: Develop and validate prediction models that consider lifestyle-, genetic-, treatment- and patient-factors that identify sub-groups of pediatric cancer survivors at high risk of adverse cardiometabolic outcomes.	SJLIFE participants of European ancestry, aged ≥18 years, and ≥10 years from diagnosis who provided a sample for WGS Validate in CCSS (not approved yet)	Pending				Approved by CCSP; analysis ongoing
Zhang/Wang	A study of clonal hematopoiesis in long-term survivors of childhood cancer	Easton Ma Yasui Wilson Ness Hudson Robison	Hagiwara	Characterize driver mutations for clonal hematopoiesis (CH); Analyze treatment risk factors for CH; Evaluate associations with chronic health conditions among SJLIFE survivors						Analysis ongoing Manuscript under development

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Sapkota	Genome-wide polygenic score for coronary artery disease in childhood cancer survivors	Liu Bhatt Ehrhardt Wilson Wang Zhang Armstrong Hudson Robison Mulrooney Yasui	Sapkota/Liu	To assess previously validated general population GPS for CAD risk and its potential interplay with survivor-specific factors in childhood cancer survivors in the SJLIFE	SJLIFE survivors of European ancestry with WGS data					Accepted by JACC:CardioOncology;
Sapkota	Prediction and validation of severe obesity in adult survivors of childhood cancer	Qiu Li Wilson Wang Zhang Leisenring Morton Bhatia Armstrong Hudson Robison Delaney Yasui	Sapkota/Qiu/Li	To characterize severe obesity in childhood cancer survivors To develop a prediction model for severe obesity including clinical, lifestyle and genetic risk factors in SJLIFE and validate in CCSS	Survivors from SJLIFE and CCSS with genome-wide data					Accepted in principle by Nature Medicine
Sapkota/ Burridge	Predicting and Preventing chemotherapy-induced cardiotoxicity in African American children [R01 CA261898 (Burridge/Sapkota)]	Yasui Hudson Robison	Sapkota	Aim 1: To rigorously phenotype drug response in hiPSC-CMs derived from 100 African American adult survivors of childhood cancer who have received doxorubicin. Aim 2: To assess gene expression, splicing and chromatin accessibility responses to doxorubicin between hiPSC-CMs of AA survivors with and without DIC, discover novel SNPs by dQTL mapping, validate with hiPSC-CMs, and discover cardioprotectants. Aim 3: To build a user-friendly tool for clinical DIC risk prediction.	SJLIFE survivors of African ancestry exposed to doxorubicin, no chest RT with WGS data and have PBMC sample for hiPSC generation					100 AA survivors sent to Paul; experiments underway

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Genetics Working Group										
Principal Investigator/ Senior Mentor	Concept Title	Co-Investigators	Statistician/ Analyst	Objective	Eligibility Criteria	Date CPC Investigator Review	BIMS#/ SJLIFE#	Abstract	Date of Data Freeze	Analysis/ Manuscript Progress
Sapkota/ Burridge	Validating novel locus on chromosome 6 associated with cardiomyopathy among European American survivors, using patient-specific hiPSC-cardiomyocytes	Yasui Hudson Robison	Sapkota	To validate chromosome 6 locus for cardiomyopathy in EA survivors and investigate underlying molecular mechanisms	SJLIFE survivors with and without risk allele of the top SNP at chromosome 6; exposed to ≥ 250 mg/m ²					Experiments underway (plan to have manuscript drafted by end of the year)
Sapkota/ Burridge	Validating novel loci on chromosome 1 associated with cardiomyopathy among African American survivors, using patient-specific hiPSC-cardiomyocytes	Yasui Hudson Robison	Sapkota	To validate novel risk loci for cardiomyopathy in AA survivors and investigate underlying molecular mechanisms	SJLIFE survivors with and without risk allele of the top variant at chromosome 1; exposed to ≥ 250 mg/m ²					Experiments underway (plan to have manuscript drafted by end of the year)
Sapkota/ Ness/ Bass/ Burridge	Assessing the genomic basis of cisplatin-induced ototoxicity using patient-specific hiPSCs	Yasui Hudson Robison	Sapkota	To evaluate if patient-specific hiPSC-inner hair cells recapitulate in vivo cisplatin-induced ototoxicity	Have WGS data; exposed to ≥ 300 mg/m ² of cisplatin; no exposure to CRT, ear RT; carboplatin, oxaliplatin, aminoglycosides or noise exposure					PBMCs of 10 eligible survivors have been sent to Paul; experiments underway
Sapkota/ Krull/ Burridge	Assessing the genomic basis of methotrexate-induced neurotoxicity using patient-specific hiPSCs	Yasui Hudson Robison	Sapkota	To evaluate if patient-specific hiPSC-brain cells (neurons, microglia, astrocytes and oligodendrocytes) recapitulate in vivo methotrexate-induced neurotoxicity	Have WGS data; exposed to intrathecal and high-dose methotrexate with no exposure to CRT and no history of relapse, second malignancy and neurologic injury to cancer therapy					PBMCs of 10 eligible survivors have been sent to Paul; experiments underway
Sapkota	The role of proteome and metabolome in anthracycline-induced cardiotoxicity	Peng Poudel Yasui Hudson Robison	Poudel Sapkota	To examine proteomic and metabolomic profiles between survivors with and without cardiomyopathy	Have WGS data and serum samples; exposed to anthracyclines; no exposure to chest RT					Pilot experiment on 16 survivors complete; experiments on additional 200 survivors are currently underway
Sapkota	Whole blood-based gene expression, genetic variants and cardiomyopathy in survivors	Yasui Hudson Robison	Sapkota	To assess differential whole blood-based gene expression with respect to cardiomyopathy and integrate them with genetic variants and DNA methylation	SJLIFE survivors of European ancestry with WGS and RNA-seq data; exposed to cardiotoxic therapies					Analysis resumed using RNAseq data on 94 EA and 90 AA survivors

WG update: 5/23/2022			CCSP CONCEPT/ANCILLARY STUDY REGISTRY Genetics Working Group			Working Group Chair: Yadav Sapkota and Zhaoming Wang				
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Im/Yuan	Treatment-specific genetic risk scores for late effects prediction in childhood, adolescent, and young adult cancer survivors	Yasui Mulrooney Wang Armstrong Hudson Robison		Create a reference gene-by-treatment (GxT) interaction effects catalog for a range of treatments and subsequent malignant neoplasm, cardiovascular, and endocrine phenotypes; develop polygenic risk scores featuring GxT effects among childhood/AYA cancer survivors	All participants in SJLIFE/CCSS with genotype and phenotype data data					R21 funded by NCI, Analyses ongoing; additional SN phenotypes are being considered
Green	Case series of Patients with Concomitant Wilms Tumor and Possible Polycystic Kidney Disease	Fleming Sapkota Flasch Zhang Nichols Yang Murphy Graetz Santiago Krasin McCarville Wang Mostafavi Bissler Ness Robison Hudson		To report a case series of patients with concomitant Wilms tumor and ADPKD, a previously undescribed clinical association To query existing germline sequencing data (SJLIFE research germline genomic sequencing data, clinical germline genetic test reports) to confirm alterations in genes known to be associated with ADPKD, including <i>PKD1</i> , <i>PKD2</i> , <i>GANAB</i> , and <i>DNAJB11</i> in SJLIFE participants SJL1295409, SJL1740509, SJL1753209, SJL2505509, SJL5010209, and SJCRH patient SJWLM032765 To query existing germline sequencing data (SJLIFE research germline genomic sequencing data, clinical germline genetic test reports) to confirm the presence of P/LP variants in one or more Wilms tumor associated genes in those participants identified to have P/LP variants in an ADPKD-associated gene						Concept proposal approved at the Genetics WG; IRB submission in process

Replication analyses

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M. Eileen Dolan	The Platinum Study - a GWAS for cisplatin-induced ototoxicity (tinnitus) among testicular cancer survivors	Omar El Charif; Matthew R. Trendowski; Lois B. Travis	Yadav Sapkota; Qi Liu; Carrie Howell	Replication analysis	European ancestry					Our results did not replicate (0/2 SNPs) but they went ahead and published their findings without acknowledging our extensive effort
M. Eileen Dolan	GWAS of radiation-induced hearing loss or tinnitus in the CCSS	Matthew R. Trendowski; Yutaka Yasui; Jessica Baedke; Yadav Sapkota; Smita Bhatia; Gregory T. Armstrong; Kevin Oeffinger; Wendy Leisenring; Lindsay Morton	Jessica Baedke; Yadav Sapkota	Replication analysis	European ancestry					Replicated 1/6 SNPs; manuscript published in Cancer. 2021 July 19. doi: 10.1002/cncr.33775.(https://pubmed.ncbi.nlm.nih.gov/34286861/)
Melissa Richard; Maria M. Gramatges	A genome-wide association study for frailty in adult survivors of childhood cancer in the CCSS	Philip Lupo; Samah Hayek; Yutaka Yasui; Zhaoming Wang; Lindsay Morton; Eric Chow; Kevin Oeffinger; Rebecca Howell; Les Robison; Greg Armstrong; Smita Bhatia; Kiri Ness;	Yadav Sapkota; Jessica Baedke	Replication analysis						Of the 6 SNPs requested to replicate (2 GWS and the remaining near GWAS); 2 replicated in SJLIFE; results were sent to them; additional analyses based on self-reported data
Peter Bazeley; Smita Bhatia	A GWAS for siring pregnancy in the CCSS	Sarah Worley; Bo Hu; Dennis Kuo; Greg Armstrong	Yadav Sapkota	Replication analysis						Did not replicate (0/2 SNPs); results were shared to investigators; submitted to CEBP (as NULL results)

Donghao Lu; Christopher Recklitis	A GWAS for posttraumatic stress symptoms and disorder in the CCSS	Unnur Valdimarsdottir; Melissa Hudson; Les Robison; Yutaka Yasui; Todd Gibson; Lindsay Morton; Carmen Wilson; Greg Armstrong; Wendy Leisenring; Smita Bhatia; Kevin Krull	Yadav Sapkota; Nan Li	Replication analysis						Accepted in Translational Psychiatry
Kala Kamdar; Philip Lupo	A GWAS for BMI in CCSS survivors	Melissa Richard; Austin L. Brown; Vidal M. Arroyo; John W. Belmont, Michael E. Scheurer, Kayla L. Foster, Kathleen D. Kern, Melissa M. Hudson, Wendy M. Leisenring, M. Fatih Okcu, Yutaka Yasui, Lindsay M. Morton, Stephen J. Chanock, Leslie L. Robison, Gregory T. Armstrong, Smita Bhatia, Kevin C. Oeffinger	Yadav Sapkota; Nan Li	Replication analysis						1/23 replicated; results were shared; Published in Cancer. 2021 Jan 15;127(2):310-318 (https://pubmed.ncbi.nlm.nih.gov/33048379/)
Melissa Richard; Maria M. Gramatges	GWAS for subsequent thyroid cancer in CCSS	Philip J. Lupo, Lindsay M. Morton, Yutaka Yasui, Michael A. Arnold, Joseph P. Neglia, Lucie M. Turcotte, Wendy M. Leisenring, Stephen J. Chanock, Joshua N. Sampson, Gregory T. Armstrong, Leslie L. Robison, Smita Bhatia	Yadav Sapkota; Nan Li	Replication analysis						1/1 replicated; results shared; Results published in PLoS One 2020 Feb 10;15(2):e0228887 (https://pubmed.ncbi.nlm.nih.gov/32040538/)
Alana Morrison; Daiel Bowers	GWAS for MI and stroke in CCSS	Greg Armstrong; Smita Bhatia; Yutaka Yasui; Melissa Hudson; Les Robison	Yadav Sapkota; Nan Li	Replication analysis						0/24 replicated; results shared

Nisha Rathore; Danielle Friedman	GWAS for diabetes in CCSS	Greg Armstrong; Smita Bhatia; Yutaka Yasui; Melissa Hudson; Les Robison	Yadav Sapkota; Nan Li	Replication analysis						Submitted to JCO PO
Maja Krajcinovic	Whole-exome based study for neuropsychological outcomes in survivors of pediatric ALL survivors - the PETALE study		Yadav Sapkota; Jessica Baedke	Replication analysis						Of the 7 SNPs, 1 showed borderline significance but in a different genetic model that the discovery model; Results published in PLOS One
Zhaokang Cheng	Replicating findings for doxorubicin- induced cardiotoxicity from animal studies		Yadav Sapkota	Replication analysis						Under revision at JACC CardioOncology

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