

Study and PI	Description	Enrollment Criteria	Who to contact
Head and Neck			
Yarbrough-LCCC 2044: Prospective observational study to validate circulating HPV DNA and prognostic genomic biomarkers in HPV-associated OPSCC	Study duration of up to 5 years using blood and tissue collection processed through TPF to look for biomarkers in patients being treated for HPV related H&N cancer. Patients will also complete QoL surveys throughout the study.	-T0-T2 N2a-N3 M0 or T3-T4 N0-N3 M0 (AJCC 7 th edition) -Biopsy proven SCC of the oropharynx or unknown primary -No prior history or therapy for the HPV+ HNSCC that makes them a candidate for this study	Study Coordinator/group: Tuvara King (OCTR) (Tking@med.unc.edu , 919-843-5210)
Sheth- LCCC1835: Circulating Tumor DNA (ctDNA) in Locally Advanced Head and Neck Squamous Cell Carcinoma	Circulating tumor DNA (ctDNA) is a blood-based test that measures dying or dead cancer cells that are already circulating in the blood. In this study, we will enroll patients who are planning to receive surgery to remove their head and neck cancer and measure the levels of ctDNA at several timepoints throughout the study.	Newly diagnosed, histologically confirmed SCC of the head and neck, including the following subtypes: oral cavity, oropharynx, larynx planning to undergo gross total resection of the primary tumor with curative intent at UNC-CH hospital	Study Coordinator: Rose Wilgus (OCTR) (rose_wilgus@med.unc.edu)
Shen- NBTXR3-1100: A Phase I Study of NBTXR3 Activated by Radiotherapy for Patients with Advanced Cancers Treated With An Anti-PD-1 Therapy	The 1100 study is an open-label, Phase I, prospective clinical study to assess the safety of intratumoral injection of NBTXR3 activated by radiotherapy in combination with anti-PD-1 therapy among 3 cohorts: 1) R/M HNSCC, 2) lung mets from any primary eligible for anti-PD1, or 3) liver mets from any primary eligible for anti-PD1	-May be anti-PD1 naïve or anti-PD1 non-responders. -May have 1 or multiple mets, only 1 needs to be injectable and amenable to SBRT	Study Coordinator: Stephanie Corbett (CPO) (stephanie_corbett@med.unc.edu , Phone #: 919-966-0581 Pager #: 919-393-2719)
Shen- Nanoray-312: A phase III pivotal study of NBTXR3 activated by investigator's choice of radiotherapy alone or radiotherapy in combination with cetuximab for platinum-based chemotherapy-ineligible elderly patients with locally advanced head and neck squamous cell carcinoma	This is a global, open-label, randomized, 2-arm, Investigator's choice, Phase 3 study to investigate the efficacy (performance) and safety of NBTXR3/RT±cetuximab versus RT±cetuximab in treatment-naïve, platinum-based chemotherapy-ineligible elderly participants with locally advanced head and neck squamous cell carcinoma (LA-HNSCC).	-Primary site: oropharynx, oral cavity, hypopharynx (any p16 status) -T3-T4 AJCC 8th edition -Has at least 1 lesion amenable for intratumoral injection (1 or 2 lesions can be injected, the primary site must be one lesion and a nodal lesion 3-10cm can also be injected)	Study Coordinator: Stephanie Corbett (CPO) (stephanie_corbett@med.unc.edu , Phone #: 919-966-0581 Pager #: 919-393-2719)

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Breast			
Casey/Morse- LCCC 2104: Comparison of Adjuvant Monotherapy with Endocrine Therapy or Accelerated Partial Breast Irradiation Following Lumpectomy for Low Risk Breast Cancer Patients Over 65 (CAMERAN)	Study randomizing women over 65 with early stage breast cancer to receive radiation or hormonal therapy and then evaluate and compare quality of life and function in both groups at 12 months after lumpectomy.	<ul style="list-style-type: none"> -De novo invasive carcinoma of breast. -Pathological T1 (pT1) stage, Clinical or pathological N0, overall tumor Grade 1 or 2 -ER/PR + (greater than or equal to 10% ER and PR by IHC staining) -Human epidermal growth factor receptor 2 (HER2) according to ASCO/CAP guidelines (0 or 1+ following IHC staining or proven negative by in-situ hybridization [ISH]) -No pre- or post-operative systemic chemotherapy while on study or current ongoing treatment with anti-hormonal agents or hormonal replacement therapy -No synchronous bilateral breast cancer, Multifocal or multicentric tumor, or prior breast or thoracic radiation 	Study Coordinator: Jessica Buddenbaum (OCTR) jessica_buddenbaum@med.unc.edu , 919-740-5678
Gupta/Casey: Pre-op Pembro + Radiation Therapy in Breast Cancer (P-RAD)	This research trial is studying a combination of neoadjuvant radiotherapy (RT), immunotherapy (pembrolizumab) and chemotherapy for lymph node-positive, triple negative (TN) or hormone receptor positive/HER2-negative breast cancer	<ul style="list-style-type: none"> -Patients with TNBC or HR+/HER2- BC - non-metastatic, T1*-T2 and N1-3 - Primary breast tumor measuring ≥ 1.5 cm in maximal diameter - Breast-conserving surgery or mastectomy +/- reconstruction is planned following NAC 	Study Coordinator: Rosemarie Baston (CPO) rosemarie_baston@med.unc.edu , 919-517-3534
Casey-CCTG MA.39: Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive and T3N0 Breast Cancer	International multi-center, randomized, non-inferiority phase III trial evaluating regional radiotherapy (RT) [defined as RT to regional nodes following breast conserving surgery (BCS) or RT to the chestwall and regional nodes following mastectomy] in patients with ER +ve biomarker low risk breast cancer [defined as Oncotype DX recurrence score ≤ 25] and limited nodal disease or T3N0 that have had BCS, or mastectomy and will receive endocrine therapy for 5 years.	<ul style="list-style-type: none"> -women age ≥ 35 with newly diagnosed histologically proven invasive carcinoma of the breast with no evidence of metastases, staged as per site standard of care, planning to start RT within 16 weeks of surgery if not getting chemo, or within 12 weeks of last dose of adjuvant chemotherapy -Patients must have been treated by BCS or mastectomy with clear margins of excision - Must consent to collection of blood samples and tumor tissue (fresh or already collected) -Nodal macrometastases (> 2 mm) treated by axillary dissection must have 1-3 positive axillary nodes (macrometastases, > 2 mm) or treated by SLNB alone must have only 1-2 positive axillary nodes (macrometastases, > 2 mm) 	Study Coordinator: Claire Kowalczyk (CPO) Claire.Kowalczyk@med.unc.edu , Pager: 9192161023 Phone: 919-962-7337

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GYN			
Weiner- LCCC 2052: Patient related outcomes for gynecological radiation oncology (PRO-GRO)	Evaluating whether implementing patient related outcome measurements (PROM) before, during, and after radiation for GYN cancer is feasible in a high volume GYN radiation oncology clinic.	-Gynecologic cancer being treated by radiation at UNC -English speaking -Not a prisoner	Study Coordinator: Victoria Xu (RORG) (victoria_xu@med.unc.edu , 984-974-8744)
Sud- LCCC 2051: Plasma circulating tumor HPVDNA and Transrenal HPVDNA as minimally invasive biomarkers for cervical cancer detection and surveillance following definitive treatment	Plasma samples and pathology results will be analyzed to determine plasma cHPVDNA levels and TrHPVDNA levels in urine using a dPCR assay	Women who are not pregnant and newly diagnosed with cervical cancer	Study Coordinator: Melissa Knutsen (OCTR) (melissa_knutsen@med.unc.edu , pager: 919-826-0517)
Sud- LCCC1928: Application of plasma circulating HPV DNA testing to management of cervical intraepithelial neoplasia	Study trying to determine if you can measure the levels of cHPVDNA in women who may have dysplasia coming to unc gyn clinics who will fall into 3 cohorts (normal/healthy, CIN 1, or CIN 2-3). These will be determined using SOC pap smears and will be compared with study blood and pap smear collections.	-Women who are not pregnant -No history of previously treated cervical cancer **Only enrolling through Gyn clinic with Lisa Rahangdale	Study Coordinator: Tuvara King (OCTR) (Tiking@med.unc.edu , pager: 919-826-0517)

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CNS			
Shen- GTM 101: A Multicenter Observational Study of GammaTile™ Surgically Targeted Radiation Therapy (STaRT) in Intracranial Brain Neoplasms	Non-interventional registry study to evaluate real-world clinical outcomes and patient reported outcomes that measure the effectiveness and safety of GammaTiles for up to 5 years post implant.	-Patients who undergo maximum safe resection of intracranial neoplasm(s) AND implantation of GammaTiles. -Must be able to undergo pre-operative and post-operative imaging for disease and implant assessment	Study Coordinator: Olivia Morton (RORG) (Olivia_roberts@med.unc.edu , 984-974-8441)
Shen- LCCC 1844: MR Imaging Biomarkers for Radiation-induced Neurocognitive Decline Following Stereotactic Radiosurgery of Newly Diagnosed Brain Metastases: An Observational Pilot Study	To quantify longitudinal changes in radiation-induced white matter (WM) injury in patients with brain metastasis treated with stereotactic radiosurgery (SRS) using MRI and neurocognitive assessments over the course of one-year post-RT	-Histologic diagnosis of cancer and newly diagnosed brain metastasis being treated with SRS. Any extent of cranial disease permitted. -Anticipated life expectancy at least 1 year -No prior radiation or severe injury to head or brain	Study Coordinator: Olivia Morton (RORG) (Olivia_roberts@med.unc.edu , 984-974-8441)
Shen- BRE18-360: Phase I/II Study of Stereotactic Radiosurgery with Concurrent Administration of DNA Damage Response (DDR) Inhibitor (Olaparib) Followed by Adjuvant Combination of Durvalumab (MEDI4736) and Physician's Choice Systemic Therapy in Subjects with Breast Cancer Brain Metastases	Phase I/II study to evaluate safety and efficacy of SRS with concurrent olaparib, followed by durvalumab + physician's choice systemic therapy for patients with brain metastasis from TNBC (any BRCA status) or HER2-neg BC with germline or somatic BRCA mutation.	-Diagnosis of TNBC (any BRCA status), or HER2-negative with germline or somatic BRCA mutation -New diagnosis of brain metastasis by MRI, with a plan to undergo SRS (up to 10 metastases with total brain metastases volume ≤15cc). Patients are permitted to have undergone resection of metastasis/metastases if at least 1 other intact metastasis planned for definitive SRS is present. -Patients may have had prior SRS as long as the previously treated brain metastases are stable and not planned for additional therapy. -Discrete dural lesions are allowed.	Study Coordinator: Camisha Johnson (CPO) (camisha_johnson@med.unc.edu , 919-445-4847) Prefers email
Shen- EF-32 (TRIDENT): A Pivotal Randomized, Open-Label Study of Optune® (TTFields, 200khz) Concomitant with Radiation Therapy and Temozolomide for the Treatment of Newly Diagnosed Glioblastoma	Randomized trial testing the effectiveness and safety of TTFields given to newly diagnosed GBM patients, concomitantly with radiation therapy and temozolomide compared to treatment with radiation therapy and temozolomide, where in both arms TTFields and maintenance temozolomide are continued following radiation therapy.	-Tissue based diagnosis of GBM - Above 22 years of age - After surgery or biopsy amenable for radiation therapy with concomitant TMZ	Study Coordinator: De'Andrea Cunningham (CPO) (deandrea_taylor@med.unc.edu , 919-962-7253)

<u>Study and PI</u>	<u>Description</u>	<u>Enrollment Criteria</u>	<u>Who to contact</u>
Dr. Shen/Quinsey- Characterizing the effect of different modalities of brain radiation on sleep, mood, and function in adult metastatic and primary brain tumor patients	To assess the prevalence of sleep disturbance over time in post-surgical metastatic brain tumor patients receiving either whole-brain radiotherapy (WBRT) or CyberKnife stereotactic radio-surgery (SRS). The study will also include patients receiving partial brain radiotherapy (PBRT) for primary brain tumors.	- Patients receiving CyberKnife radiation, whole brain radiotherapy, or partial brain/focal radiotherapy for metastatic or primary brain tumors -english speaking -KPS > 60 -no sleep medications -no diagnosis w/ sleep, mental health or substance abuse disorder	Marcus Donnelly (marcus_donnelly@med.unc.edu)
Peds/AYA			
Smitherman: UNC Childhood, Adolescent, and Young Adult Cancer Registry	A registry of childhood, adolescent, and young adult patients with cancer. This registry is for anyone diagnosed with cancer before the age of 40 years to establish a UNC-based resource for the prospective study of the long-term, treatment-related effects, particularly the early aging effects, of cancer and its treatment.	-0-39y at diagnosis, 1-39y at enrollment -English/Spanish speaking	Study Coordinator: Daniel Kleissler (OCTR) (unccayacc@unc.edu or Epic message Daniel)
Casey: Proton and Photon Consortium Registry (PPCR)	A multi-center registry for children treated with radiation therapy receiving protons or photons	-Patients <21 years old at the start of RT treatment -May be enrolled regardless of previous or current local or systemic treatments received or disease extent -Patients may be enrolled concurrently with another study or clinical trial.	Study Coordinator: Niyati Patel (RORG) (niyati_patel@med.unc.edu, 984-974-8440)
Metastatic			
Wood (Casey/Hall)- LCCC 1948: Effects of Exercise Health Coaching in Patients with Metastatic Malignancy Receiving Radiation: A Pilot Study	Patients are randomized to HealthScore health coaching vs. routine care. HealthScore pairs participants with a health coach for 6 months to address physical, psychosocial, nutritional aspects of care.	-Planned to receive radiation for metastatic disease -KPS 70 or greater -Age > 18 -English-speaking	Study Coordinators: Carly Bailey (carly_bailey@med.unc.edu) or Bri Castrogivanni (brianna_castrogivanni@med.unc.edu)

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Non-Oncology			
Yanagihara- Patient Reported Outcomes following Low-dose irradiation for Osteoarthritis (PRO-LO): A single-arm prospective registry	Non-interventional registry collecting data related to patient reported outcomes (pain, function, quality of life, toxicity) with the goal of optimizing approaches to management with radiation therapy and clinical care during follow up for patients being treated for OA	<ul style="list-style-type: none"> -Established diagnosis of OA of at least 1 joint not including the shoulder -Inadequately controlled pain due to OA despite attempts with 2 or more other treatment modalities and Visual Analogue Pain Score of 4 or greater. -Will undergo radiation as part of their standard of care for OA. -At least 60 years old 	Study Coordinator: Victoria Xu (RORG) (victoria_xu@med.unc.edu ,984-974-8744)
GI			
Yanagihara- PACER (Pancreatic AdenoCarcinoma with Electron intraoperative Radiation therapy): A Phase II study of electron beam intraoperative radiation therapy following chemoradiation in patients with pancreatic cancer with vascular involvement.	Multicenter study tracking survival and how well IORT works for up to 2 years in patients with pancreatic cancer treated with chemoradiation	<ul style="list-style-type: none"> -Histologically confirmed pancreatic adenocarcinoma with vascular involvement, either borderline/ potentially resectable or locally advanced. -Previous completion of at least three (3) months of EITHER gemcitabine plus nab-paclitaxel OR FOLFIRINOX (5-fluorouracil, oxaliplatin, irinotecan and leucovorin) -Previous completion of either stereotactic-body radiation therapy (SBRT) (minimum 24 Gy) or external beam irradiation (EBRT) (minimum 45 Gy or 36 Gy in 15 fractions) 	Study Coordinator: Claire Kowalczyk (CPO) (Claire_Kowalczyk@med.unc.edu, Pager: 9192161023 Phone: 919-962-7337)
Yanagihara- LCCC 2247: Disease outcomes and toxicities in patients with gastrointestinal and sarcomatous malignancies	A single-institution, prospective, observational study of patients with gastrointestinal malignancies and sarcoma (osseous and soft tissue) who are being treated with standard of care therapies.	<ul style="list-style-type: none"> -Histological, cytological, or radiographic evidence/confirmation of a gastrointestinal malignancy or sarcoma. Prior or concurrent brain metastases are allowed. Synchronous or metachronous malignancies are allowed. -Age \geq 18 years -Patients who state they do not expect to be available or willing to follow up at expected intervals post-treatment (virtual visits are allowed) 	Study Coordinator: Victoria Xu (RORG) (victoria_xu@med.unc.edu ,984-974-8744)

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GU			
Repka- LCCC 1917: Steering Dose Inhomogeneity of Stereotactic Body Radiotherapy Towards the Lesion Defined by 68Ga-HBED-CC PSMA-PET/mpMRI in Low and Intermediate Risk Localized Prostate Cancer Patients	PSMA-PET/MRI Low and Intermediate-Risk Target Volume Pilot Study	-Histologically confirmed prostate adenocarcinoma with low or favorable intermediate risk, based on the NCCN criteria with appropriate staging (e.g. bone scan). -No Previous TURP or surgery of the prostate -No Contraindications for MRI	Study Coordinator: Flora Danquah (CPO) (flodanq@email.unc.edu, 857-204-3140)
Milowsky- LCCC2208: Pilot study to evaluate the role for circulating tumor DNA (ctDNA) in monitoring subjects with muscle-invasive bladder cancer treated with trimodality therapy	Non-interventional study testing the hypothesis that ctDNA detection is feasible in MIBC subjects treated with trimodality therapy consisting of a maximal transurethral resection of bladder tumor followed by radiation and concomitant chemotherapy and may have both predictive and prognostic value.	-A diagnosis of MIBC with SOC plan to treat with trimodality therapy (consisting of a maximal TURBT followed by radiation and concomitant chemotherapy). -Age ≥ 18 years at the time of consent. -Must have available archival tissue, if deemed insufficient the participant will be replaced. - No serious medical or psychiatric disorder that would interfere with the subject's ability to give informed consent or Incarcerated individuals.	Study Coordinator: Hannah Mabey (OCTR) (Hannah_Mabey@med.unc.edu)
Elmore-LCCC 2129: Defining the impact of telemedicine on shared decision-making surrounding treatment choice for Black patients with prostate cancer	interview study looking at Black patients' perspective about their care to better understand how an SDM model can be altered to best fit the patient's needs. Additionally, focus group discussions with clinical/research staff, patients, and patient advocates will further elucidate the feasibility and effectiveness of the modified SDM model in prostate cancer treatment decision making for Black patients.	-Identify as Black (including African American or African Ancestry) -Be at least 18 years of age -Diagnosed with localized prostate cancer (M0/no distant metastatic disease) -Seen for an initial consultation at UNC Medical Center, UNC REX, or Nash Healthcare to discuss treatment options in or after April 2020 -Identified as patients, caregivers, or prostate cancer patient advocates	Study Coordinator: Kadiata Toumbou (kadiata_toumbou@med.unc.edu)