Currently Enrolling Studies 06/06/2024

Study and PI	Description	Enrollment Criteria	Who to contact
Head and Neck			
Yarbrough-LCCC 2044: Prospective observational study to validate circulating HPVDNA 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 7th 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 (TSHS) (Tjking@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 (TSHS) (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: Bryana Roberts (bkrobert@email.unc.edu) **Or** Jasmine Jordan (jasmine_jordan@med.unc.edu)
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: Bryana Roberts (bkrobert@email.unc.edu) **Or** Jasmine Jordan (jasmine_jordan@med.unc.edu)

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Chen- MGT-AQP1-201: A Randomized, Double-Blind, Placebo-Controlled Study to Determine the Efficacy and Safety of AAV2-hAQP1 Gene Therapy in Participants with Radiation-Induced Late Xerostomia	Randomized, double-blind, placebo-controlled, multi-center study assessing the efficacy and safety of bilateral intra-parotid administration of AAV2-hAQP1 in adults with Grade 2 or Grade 3 radiation-induced late xerostomia	- Completed beam radiation therapy for head and neck cancer at least 3 years prior to the first screening visit - No history of parotid gland cancer, recurrent cancer, or a second primary cancer -An unstimulated whole saliva flow rate (mL/min) >0 (i.e., at least one drop of saliva in the collection tube) - Average screening modified XQ Total Score ≥25	Study Coordinator: Chasity McCue (FB) (chasity_mccue@med.unc.edu)
Chen: CCTG-HN.11: SPECT-CT Guided Elective Contralateral Neck Treatment (Select) For Patients With Lateralized Oropharyngeal Cancer: A Phase III Randomized Controlled Trial	This is an international multi-center, non-inferiority randomized phase III trial comparing a lymphatic mapping-guided approach for management of the contralateral neck (experimental) vs. bilateral neck RT (control) in patients with lateralized OPC.	-Patients with pathologically proven diagnosis of lateralized OPC (tonsil, tongue base, soft palate, or pharyngeal wall) not involving or crossing midline, planning to receive definitive RT or CRT with bilateral neck RT -HPV p16 positive or negative -Clinical stage T1-3 M0 (UICC/AJCC TNM 8th Edition) -ECOG of 0-2	Study Coordinator: Chasity McCue (FB) (chasity_mccue@med.unc.edu)
Shen/Fried: LCCC2244 A Phase II Randomized Assessment of Sparing Parotid Ducts via MRI Sialography for Reduced Patient Reported Xerostomia following Radiotherapy for Oropharynx Cancer	This is randomized single-center study comparing MRI-guided parotid ductal sparing to standard of care mean parotid gland sparing in terms of patient reported outcomes in patients receiving radiotherapy for oropharynx cancer.	-T0-4, N0-3, M0 disease (AJCC 7th or 8th edition) of the oropharynx (this includes patients with head and neck cancer of unknown primary origin, often categorized as T0 disease, who will be treated with radiotherapy to the oropharynx) planned for definitive radiotherapy +/- chemotherapy -No contraindications to receiving MRI	Study Coordinator: Tuvara King (TSHS) (Tjking@med.unc.edu, pager: 919-826-0517)

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Study and PI	Description	Enrollment Criteria	Who to contact
Breast			
Casey/Morse- LCCC 2104: Comparison of Adjuvant Monotherapy with Endocrine Therapy or Accelerated Partial Breast Irradiation Following LumpeFBmy 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 lumpeFBmy.	-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 faFBr 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 (TSHS) (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	-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 masteFBmy +/- reconstruction is planned following NAC	Study Coordinator: Taylor Pierce (FB) (tepierce@email.unc.edu or epic message)
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 masteFBmy] 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 masteFBmy and will receive endocrine therapy for 5 years.	-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 masteFBmy 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: Chasity McCue (FB) (chasity_mccue@med.unc.edu)

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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 ctHPVDNA 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 (TSHS) (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 (TSHS) (Tjking@med.unc.edu, pager: 919-826-0517)

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CNS			
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 (FB) (camisha_johnson@med.unc.edu, 919-445-4847) Prefers email
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)

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Study and PI	Description	Enrollment Criteria	Who to contact
Shen-GTM 102: A Phase 3 Randomized Controlled Trial of Post-Surgical Stereotactic Radiotherapy (SRT) versus Surgically Targeted Radiation Therapy (STaRT) with Gamma Tile for Treatment of Newly Diagnosed Metastatic Brain Tumors.	To compare surgical tumor removal followed by stereotactic radiotherapy (SRT) against surgical tumor removal followed by intraoperative radiation therapy utilizing GammaTiles	- No sensitivity to bovine derived materials (collagen) - One to four newly diagnosed brain metastases, identified on the screening MRI, from an extracranial primary tumor that have not been previously treated -primary lesion planned for GTR and between 2.5-5cm on MRI -Non-primary lesions must be <4.0cm in max extent screening MRI and plan to be treated with SRT -All mets located >5mm from optic chiasm and outside brainstem - Previous and/or concurrent systemic therapy allowed - KPS score of ≥70 - Stable systemic disease or reasonable systemic treatment options predicting a life expectancy of ≥6 months. - No primary germ cell tumor, small cell carcinoma, lymphoma, or leptomeningeal metastasis	Study Coordinator: Chasity McCue (FB) (chasity_mccue@med.unc.edu)
Peds/AYA/ Lymphoma			
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: (TSHS) (unccayacc@unc.edu)
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)

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Metastatic			
LCCC 2303: University of North Carolina at Chapel Hill Metastatic Cancer Radiation Therapy Registry	A repository of clinical outcomes of participants evaluated to receive radiation therapy for their metastatic cancer treatment. Clinical data, radiological assessments and patient reported outcomes will be collected.	-Has been diagnosed with or is suspected to have metastatic cancer. -Age ≥ 18 years at the time of consent. -Evaluated to receive radiation therapy as part of their standard of care treatment plan	Study Coordinators: Olivia Morton (RORG) (Olivia_roberts@med.unc.edu, 984-974-8441
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	-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)
Lung			
Weiner: NRG-LU088: Phase III prospective randomized trial of primary lung tumor stereotactic body radiation therapy followed by concurrent mediastinal chemoradiation for locally advanced non-small cell lung cancer	Randomized trial for patients with locally advanced inoperable node-positive non-small cell lung cancer stage II or III who will receive either image guided, motion-managed conventional radiotherapy to the primary tumor and nodal metastases or after image guided, motion-managed stereotactic body radiation therapy (SBRT) to the primary tumor followed by conventionally fractionated radiotherapy to nodal metastases, both given with concurrent platinum-based chemotherapy	-Pathologically (histologically or cytologically) proven diagnosis of Stage II or III (AJCC Eighth Edition) non-small cell lung cancer (NSCLC) with known PD-L1 status prior to registration. - Must have an identified primary tumor and at least one nodal metastasis -Must be deemed clinically appropriate for curative intent definitive combined modality therapy based on imaging or physical exam -No evidence of distant metastases based on FDG PET/CT scan obtained within 60 days of registration. -Primary tumor ≤ 7 cm	Study Coordinator: Jordan Hairston (FB) (jordan_hairston@med.unc.edu)

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GI			
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.	-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 ≥ 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)
Yangihara: Development of a circulating tumor DNA fragmentomics assay for monitoring treatment response in patients with hepatocellular carcinoma (DRAFTR-ETERNITY sub)	Develop a novel bioinformatics platform to quantify circulating tumor DNA (ctDNA) fragmentomics in patients with hepatocellular carcinoma (HCC)	-Age greater than or equal to 18 years -MRI within 2 months of study entry demonstrating radiographic diagnosis of HCC (LIRADS-4, LIRADS-5, and LIRADS TR-viable disease are allowed) -All MRI lesions treated (i.e., no lesions that are clinically considered to be viable cancer were intentionally untreated) -Not pregnant within 12 months prior to any study blood draw	Study Coordinator: Melissa Knutsen (TSHS) (melissa_knutsen@med.unc.edu, pager: 919-826-0517)
Sarcoma			
Yanagihara-LCCC 2250: Safety, Efficacy, and Mechanism of Pre-operative Spatially Fractionated Radiation Therapy in Patients with Extremity Soft Tissue Sarcoma: A Pilot Study	Any patient with extremity sarcoma 5 cm or larger who is planned to receive pre-op radiation and resection of the primary mass	-Low burden M1 & prior resection if there is 5 cm of residual/recurrent tumor -No neoadjuvant chemo or prior RT to tumor	Study Coordinator: Chasity McCue (FB) (chasity_mccue@med.unc.edu)

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GU			
Repka- NRG-GU010: Parallel phase III randomized trials of genomic-risk stratified unfavorable intermediate risk prostate cancer: de-intensification and intensification clinical trial evaluation (guidance)	Randomized trial evaluating the use of a Decipher score to guide ADT usage in patients with unfavorable intermediate risk prostate cancer.	- Pathologically (histologically or cytologically) proven diagnosis of adenocarcinoma of the prostate - at least one intermediate risk faFBr (IRF) - ONE or more 'unfavorable' intermediate-risk designators - Absence of high-risk features - Clinically negative lymph nodes (N0) as established by conventional imaging (pelvic +/- abdominal CT or MRI - No previous radical surgery (prostateFBmy) or any form of curative-intent ablation whether focal or whole-gland (e.g., cryosurgery, HIFU, laser thermal ablation, etc.), RT to the porstate/pelvis, hormal therapy, or bilateral orchieFBmy	Study Coordinator: Chasity McCue (FB) (chasity_mccue@med.unc.edu)
Sud-LCCC 2032: The effects of short chain fatty acid administration on the quality of life and treatment-related toxicities in subjects receiving abdominopelvic radiotherapy: A randomized controlled study	A placebo controlled, Phase II, double blind, randomized study with a Phase I safety run-in (single blind) to assess the efficacy of SCFA oral capsules for reduction of incidence and severity of patient reported RT-induced acute GI toxicity during abdominal or pelvic RT.	- Histological or cytological evidence/confirmation of GI, urologic or gynecologic malignancy that will be treated with minimum dose of 40Gy (equivalent dose in 2Gy per fraction or EQD2) via 3D conformal fields or IMRT to abdomen or pelvis (multimodality treatment with surgery, chemotherapy is permissible) -ECOG ≤ 2 -No prior abdominopelvic RT, CHF, active CNS metastases, or nut allergy	Study Coordinator: Chasity McCue (FB) (chasity_mccue@med.unc.edu)