

Study and PI	Description	Enrollment Criteria	Who to contact	Nursing Duties
Head and Neck				
<p>Yarbrough-LCCC 2044: Prospective observational study to validate circulating HPV DNA and prognostic genomic biomarkers in HPV-associated OPSCC</p>	<p>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.</p>	<p>-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</p>	<p>Study Coordinator/group: Tuvara King (CTO) (Tjking@med.unc.edu, 919-843-5210)</p>	<ul style="list-style-type: none"> Blood draw before RT and then at most follow ups- however will primarily use phlebotomy
<p>Sheth- LCCC1835: Circulating Tumor DNA (ctDNA) in Locally Advanced Head and Neck Squamous Cell Carcinoma</p>	<p>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.</p>	<p>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</p>	<p>Study Coordinator: Adrianna Warner (CTO) (Adrianna_warner@med.unc.edu, 919-966-7847)</p>	<ul style="list-style-type: none"> Blood draw post-RT and every 3 months up to 2 years-however will primarily use phlebotomy
<p>Shen- NBTXR3-1100: A Phase I Study of NBTXR3 Activated by Radiotherapy for Patients with Advanced Cancers Treated with An Anti-PD-1 Therapy</p>	<p>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</p>	<p>-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</p>	<p>Study Coordinator: Yanni-Taylor Shaw (CTO) (yanni-taylor_shaw@med.unc.edu)</p>	<ul style="list-style-type: none"> Screening day blood draw and vitals Injection day w/ serial PK collection and vitals Blood draw and vitals weekly during RT Blood draw and vitals every 6 weeks for year 1 and every 12 weeks year 2

Study and PI	Description	Enrollment Criteria	Who to contact	Nursing Duties
<p>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</p>	<p>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).</p>	<p>-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)</p>	<p>Study Coordinator: Samantha Bagnato (CTO) samantha_bagnato@med.unc.edu, 919-445-4972)</p>	<ul style="list-style-type: none"> • Screening day blood draw and vitals • Injection day w/ serial PK collection and vitals (depends on randomization) • Blood draw and vitals weekly during RT
<p>Chen- MGT-AQP1-201/202: 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</p>	<p>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</p>	<p>- 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</p>	<p>Study Coordinator: Erin Jennings (CTO) erin_jennings@med.unc.edu or epic message)</p>	<ul style="list-style-type: none"> • Vital signs once a month for 3 months • Occasional blood draw at a single time point-however will primarily use phlebotomy
<p>Shen: CCTG-HN.11: SPECT-CT Guided Elective Contralateral Neck Treatment (Select) For Patients With Lateralized Oropharyngeal Cancer: A Phase III Randomized Controlled Trial</p>	<p>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.</p>	<p>-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</p>	<p>Study Coordinator: Chasity McCue (CTO) chasity_mccue@med.unc.edu</p>	<ul style="list-style-type: none"> • N/A

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<p>Shen-EA3191: A Phase II Randomized Trial of Adjuvant Therapy with Pembrolizumab after Resection of Recurrent/Second Primary Head and Neck Squamous Cell Carcinoma (HNSCC) with High Risk Features</p>	<p>Phase II trial studying the effect of pembrolizumab alone compared to the usual approach (chemotherapy [cisplatin and carboplatin] plus radiation therapy) after surgery in patients with HNSCC that has come back (recurrent) or patients with a second head and neck cancer that is not from metastasis (primary).</p>	<p>-Between 18 and 79 years of age, ECOG PS 0-1 -Locoregionally recurrent or second primary HNSCC (oral cavity, oropharynx, larynx, hypopharynx) in previously radiated field -Had surgery with gross total resection (must be randomized within 8 weeks of surgery) - High risk disease defined as positive margins and/or extra nodal extension (ENE) -No evidence of distant disease based on baseline imaging done within 28 days prior to randomization -Has not received anti-PD-1/PD-L1 therapy for recurrent disease; if anti-PD-1/PD-L1 was received as part of the initial upfront curative intent treatment, the last dose must have been given greater than 1 year prior to randomization.</p>	<p>Study Coordinator: Yanni-Taylor Shaw (CTO) (yanni-taylor_shaw@med.unc.edu)</p>	<ul style="list-style-type: none"> N/A
<p>Fried-LCCC 2444: A Phase II Randomized Assessment of Sparing Parotid Ducts via MRI Sialography for Reduced Patient Reported Xerostomia following Radiotherapy for Oropharynx Cancer</p>	<p>Phase II, single-center, double masked, parallel arm, randomized controlled clinical trial comparing MRI-guided parotid ductal sparing to standard of care mean parotid gland sparing in terms of patient-reported xerostomia outcomes in subjects receiving definitive radiotherapy for oropharynx cancer.</p>	<p>-T0-4, N0-3, M0 cancer (AJCC 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 such as: implanted electrical devices, pregnancy, and significant quantities of metal in the head/neck as determined by the patient's treating physician and ultimately the MRI technologist administering the MRI. -No patients with Sjogren's disease or baseline xerostomia (CTCAE > 0 for dry mouth), lesions involving the salivary glands on diagnostic imaging, an allergy to lemon juice, or prior lifetime history of radiation therapy to the head and neck</p>	<p>Study Coordinator: Tuvara King (CTO) (Tjking@med.unc.edu, 919-843-5210)</p>	<ul style="list-style-type: none"> N/A

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Breast				
<p>Casey- 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)</p>	<p>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.</p>	<p>-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</p>	<p>Study Coordinator: Harper Wilkinson (CTO) timothy_wilkinson@med.unc.edu, 919-843-0592</p>	<ul style="list-style-type: none"> N/A
<p>Gupta/Casey: Pre-op Pembro + Radiation Therapy in Breast Cancer (P-RAD)</p>	<p>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</p>	<p>-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</p>	<p>Study Coordinator: Taylor Pierce (CTO) tepiece@email.unc.edu or epic message</p>	<ul style="list-style-type: none"> N/A
<p>Casey: Preoperative Chemotherapy, Pembrolizumab and Low or High Dose Radiation in an Expansion Cohort of Node(+), Triple Negative Breast Cancer (P-RAD(+)/TN-DCT)</p>	<p>Prospective radiation dose-finding, phase 2 expansion study of the Triple Negative (TN) cohort of the multicenter randomized study P-RAD that seeks to establish the optimal dose of radiation therapy (RT) to elicit an immune response when combined with immune checkpoint inhibitor (ICI) in breast cancer patients.</p>	<p>-Age ≥ 18 years at the time of consent. -ECOG or KPS of 0 or 1 -No active infection requiring systemic therapy, prior ipsilateral invasive breast, chest wall or thoracic radiotherapy; or prior ipsilateral invasive breast cancer, contralateral breast cancer or a known additional, invasive malignancy that is progressing or required active treatment in the last 5 years.</p>	<p>Study Coordinator: Taylor Pierce (CTO) tepiece@email.unc.edu or epic message</p>	<ul style="list-style-type: none"> N/A

Study and PI	Description	Enrollment Criteria	Who to contact	Nursing Duties
<p>Casey-CCTG MA.39: Tailor RT: A Randomized Trial of Regional Radiotherapy in Biomarker Low Risk Node Positive and T3N0 Breast Cancer</p>	<p>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.</p>	<p>-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)</p>	<p>Study Coordinator: Erin Jennings (CTO) erin_jennings@med.unc.edu or epic message)</p>	<ul style="list-style-type: none"> • N/A
<p>Steele-LCCC2404: ULTRA Hypo-fractionated Adjuvant Whole Breast Radiation Therapy with Simultaneous Integrated Boost for Early-Stage Breast Cancer (H-ASSIST)</p>	<p>A prospective study to evaluate the rates of radiation-specific toxicity, quality of life, and oncologic outcomes for early-stage breast cancer and ductal carcinoma in situ treated with 5-fraction whole breast irradiation (WBI) with simultaneous integrated tumor bed boost.</p>	<p>- Women ≥ 50 years of age with confirmed de novo invasive carcinoma of breast or ductal carcinoma in situ planning to receive either SOC whole breast 3D conformal radiation therapy (3D CRT) or SOC whole breast intensity modulated radiation therapy (IMRT) with standard dose tumor bed boost. - No history of: concurrent breast reduction involving tissue rearrangement in the lumpectomy cavity, synchronous bilateral breast cancer requiring bilateral radiation therapy or prior history of ipsilateral breast or thoracic radiation, evidence of distant metastases, patients with pT4 tumors.</p>	<p>Study Coordinator: Claire Kowalczyk (CTO) Claire_Kowalczyk@med.unc.edu)</p>	<ul style="list-style-type: none"> • N/A

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CNS				
<p>Shen- LCCC 1844: MR Imaging Biomarkers for Radiation-induced Neurocognitive Decline Following Stereotactic Radiosurgery of Newly Diagnosed Brain Metastases: An Observational Pilot Study</p>	<p>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</p>	<p>-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</p>	<p>Study Coordinator: Olivia Morton (RORG) (Olivia_roberts@med.unc.edu, 984-974-8441)</p>	<ul style="list-style-type: none"> N/A
<p>Shen- GTM 101: A Multicenter Observational Study of GammaTile™ Surgically Targeted Radiation Therapy (STaRT) in Intracranial Brain Neoplasms</p>	<p>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.</p>	<p>-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</p>	<p>Study Coordinator: Olivia Morton (RORG) (Olivia_roberts@med.unc.edu, 984-974-8441)</p>	<ul style="list-style-type: none"> N/A
<p>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.</p>	<p>To compare surgical tumor removal followed by stereotactic radiotherapy (SRT) against surgical tumor removal followed by intraoperative radiation therapy utilizing GammaTiles</p>	<p>- 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</p>	<p>Study Coordinator: Erin Jennings (CTO) (erin_jennings@med.unc.edu or epic message)</p>	<ul style="list-style-type: none"> N/A

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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: Paige Bramblett (RORG) (paige_bramblett@med.unc.edu, 984-974-8440)	<ul style="list-style-type: none"> • N/A
Sud- LCCC 2310: Feasibility study of novel applications of hyaluronic acid-based rectal spacers in gynecologic malignancies	Interventional study to examine if the novel application of hyaluronic acid-based spacing gels (Barrigel) in cervical cancer patients being treated at UNC is feasible.	-Women with histological or cytological evidence of cervical cancer planned for definitive intent chemoRT with brachytherapy except for individuals with known rectal invasion (per SOC physical exam-based assessments or SOC radiographic evaluation). -ECOG 0-2 or KPS 50-100 -Subjects with a prior or concurrent malignancy whose natural history or treatment does not have the potential to interfere with the safety or efficacy assessment of the investigational regimen are eligible for this trial per principal investigator discretion. -No known allergy to hyaluronic acid-based products or have an active infection requiring systemic therapy. -Not pregnant or breastfeeding.	Study Coordinator: Erin Jennings (CTO) (erin_jennings@med.unc.edu or epic message)	<ul style="list-style-type: none"> • N/A

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Metastatic				
<p>Sud-LCCC 2303: University of North Carolina at Chapel Hill Metastatic Cancer Radiation Therapy Registry</p>	<p>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.</p>	<p>-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</p>	<p>Study Coordinator: Paige Bramblett (RORG) (paige_bramblett@med.unc.edu, 984-974-8440)</p>	<ul style="list-style-type: none"> N/A
<p>Sud-NRG-CC014: Comparing Radiation Therapy to Usual Care for Patients With High-Risk Bone Asymptomatic Metastases</p>	<p>Phase 3 randomized trial to evaluate the role of RT with palliative intent in the treatment of asymptomatic disease for patients with polymetastatic disease.</p>	<p>-Bulky site of disease in bone (≥ 2 cm). -Disease involving the hip (acetabulum, femoral head, femoral neck), shoulder (acromion, glenoid, humeral head), or sacroiliac joints. -Disease in long bones occupying up to 2/3 of the cortical thickness (humerus, radius, ulna, clavicle, femur, tibia, fibula, metacarpals, phalanges). -Disease in junctional spine (C7-T1, T12-L1, L5-S1) and/or disease with posterolateral element (pedicles and/or facet joints) involvement. - Metastatic cancer defined as more than 5 sites of radiographically-evident systemic metastatic disease (excluding intracranial disease) - ECOG 0-2 or KPS ≥ 60 -No prior RT to intended enrolled sites of disease -No epidural spinal cord compression (ESCC) ≥ Grade 1c (defined as deformation of the thecal sac with spinal cord abutment) at the enrolled bone metastasis(es). -No prior fracture at the enrolled bone metastasis(es).</p>	<p>Study Coordinator: Claire Kowalczyk (CTO) (Claire_Kowalczyk@med.unc.edu)</p>	<ul style="list-style-type: none"> Blood draw at pre tx and 3 months after registration

<u>Study and PI</u>	<u>Description</u>	<u>Enrollment Criteria</u>	<u>Who to contact</u>	<u>Nursing Duties</u>
<p>Keefe- LCCC2336: Local Radiofrequency Ablation plus External Beam Radiation for the Treatment of Painful Thoracic and Lumbar Spine Tumors (SPARC)</p>	<p>Single-arm observational trial to test the efficacy of kyphoplasty with Osteocool ablation plus SOC radiation therapy in pain reduction for patients with thoracic and lumbar spine tumors (lytic or mixed lytic/blastic).</p>	<p>-Metastatic thoracic or lumbar spine tumor. Tumor should be lytic or mixed lytic/blastic. Note: there does not need to be a fracture. -Patient reported back pain of ≥ 5 on a VAS scale. -Must be recommended for the combination treatment (kyphoplasty with Osteocool ablation plus radiation therapy) as part of clinical care. -Radiation must be "standard" but can be delivered anywhere.</p>	<p>Study Coordinator: Tracy Carroll (Radiology) (tracy_carroll@med.unc.edu, 984-974-815)</p>	<ul style="list-style-type: none"> N/A
Non-Oncology				
<p>Yanagihara- Patient Reported Outcomes following Low-dose irradiation for Osteoarthritis (PRO-LO): A single-arm prospective registry</p>	<p>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</p>	<p>-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</p>	<p>Study Coordinator: Victoria Xu (RORG) (victoria_xu@med.unc.edu, 984-974-8744)</p>	<ul style="list-style-type: none"> N/A
<p>Yanagihara- LCCC2416: Development of a circulating tumor DNA fragmentomics assay in patients without evidence of hepatocellular carcinoma</p>	<p>Non-interventional case-control biobank study collecting blood samples from patients with cirrhosis who do not have evidence of hepatocellular carcinoma to be used as a control population in a larger study of patients with hepatocellular carcinoma. Blood samples will be used as a negative control in an assay to detect circulating tumor DNA (ctDNA).</p>	<p>-Must have a documented history of cirrhosis and be willing to provide a research blood sample -No history of liver cancer or other active diagnosis of cancer or prior diagnosis (in the past 5 years) of cancer -No evidence of liver or LI-RADS 4 or 5 lesion(s) including on most recent MRI scan and no lesions suspicious for cancer on the most recent ultrasound used for study entry.</p>	<p>Study Coordinator: Claire Kowalczyk (CTO) (Claire_Kowalczyk@med.unc.edu)</p>	<ul style="list-style-type: none"> Blood draw at time of consent with SOC labs Pregnancy test if a recent one is not already in the chart

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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: (CTO) (unccayacc@unc.edu)	<ul style="list-style-type: none"> N/A
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: Paige Bramblett (RORG) (paige_bramblett@med.unc.edu , 984-974-8440)	<ul style="list-style-type: none"> N/A
Lung				
Weiner: NRG-LU008: 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: Grace Morningstar (CTO) (grace_morningstar@med.unc.edu , (919) 966-4252)	<ul style="list-style-type: none"> N/A

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<p>Weiner-JNJ-90301900NSC2001 [CONVERGE]: A Phase 2 study of JNJ-90301900 with chemoradiation and durvalumab for non-small cell lung cancer</p>	<p>A Phase 2, randomized, open-label, active-controlled study of JNJ-90301900 in combination with chemoradiation followed by durvalumab in locally advanced and unresectable Stage III non-small cell lung cancer.</p>	<ul style="list-style-type: none"> - History of pathologically (histologically or cytologically) proven diagnosis of locally advanced Stage IIIA or IIIB NSCLC within 3 months prior to enrollment. - Have at least 1 target lesion (primary lung lesion or involved lymph node[s]) per RECIST v1.1 that is amenable to intratumoral and/or intranodal injection and EBRT. - A candidate for SOC treatment of study cancer (NSCLC) by cCRT followed by consolidation durvalumab treatment. - No history of: uncontrolled illness, major cardiac events, prior intrathoracic RT that would overlap with the current study PTV; another concurrent or prior primary malignancy or prior systemic anticancer therapy within the prior 36 months at informed consent. 	<p>Study Coordinator: Claire Kowalczyk (CTO) (Claire_Kowalczyk@med.unc.edu)</p>	<ul style="list-style-type: none"> • N/A
Sarcoma				
<p>Yanagihara-LCCC 2250: Safety, Efficacy, and Mechanism of Pre-operative Spatially Fractionated Radiation Therapy in Patients with Extremity Soft Tissue Sarcoma: A Pilot Study</p>	<p>Any patient with extremity sarcoma 5 cm or larger who is planned to receive pre-op radiation and resection of the primary mass</p>	<ul style="list-style-type: none"> -Low burden M1 & prior resection if there is 5 cm of residual/recurrent tumor -No neoadjuvant chemo or prior RT to tumor 	<p>Study Coordinator: Claire Kowalczyk (CTO) (Claire_Kowalczyk@med.unc.edu)</p>	<ul style="list-style-type: none"> • N/A

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GI				
<p>Yanagihara- LCCC 2247: Disease outcomes and toxicities in patients with gastrointestinal and sarcomatous malignancies</p>	<p>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.</p>	<p>-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)</p>	<p>Study Coordinator: Paige Bramblett (RORG) (paige_bramblett@med.unc.edu, 984-974-8440)</p>	<ul style="list-style-type: none"> N/A
<p>Yanagihara: NRG-GI011: A Phase III Randomized Trial of Dose Escalated Radiation in Locally Advanced Pancreas Cancer (LAPC) Patients (LAP100)</p>	<p>Phase III randomized trial assessing the addition of dose escalated radiotherapy to chemotherapy in LAPC patients for overall survival.</p>	<p>- Must must have received 4-6 months of active chemotherapy with FOLFIRINOX (8-12 cycles) or NALIRIFOX (8-12 cycles) or gemcitabine/Nab-Paclitaxel (4-6 cycles) (1 regimen, no sequential chemotherapy). - Pathologically (histologically or cytologically) proven diagnosis of Locally advanced unresectable pancreatic ductal adenocarcinoma. - ECOG 0-2 -No active duodenal or gastric ulcers or direct tumor invasion of the bowel or stomach.</p>	<p>Study Coordinator: Claire Kowalczyk (CTO) (Claire_Kowalczyk@med.unc.edu)</p>	<ul style="list-style-type: none"> Blood draw pre-tx, every 3 months for 2 years, and then yearly for 3 more years.
GU				
<p>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)</p>	<p>Randomized trial evaluating the use of a Decipher score to guide ADT usage in patients with unfavorable intermediate risk prostate cancer.</p>	<p>- Pathologically (histologically or cytologically) proven diagnosis of adenocarcinoma of the prostate - at least one intermediate risk faCTOr (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 (prostateCTOmy) 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, hormonal therapy, or bilateral orchiemy.</p>	<p>Study Coordinator: Chasity McCue (CTO) (chasity_mccue@med.unc.edu)</p>	<ul style="list-style-type: none"> N/A

<u>Study and PI</u>	<u>Description</u>	<u>Enrollment Criteria</u>	<u>Who to contact</u>	<u>Nursing Duties</u>
<p>Rose-NRG-GU012: randomized phase II stereotactic ablative radiation therapy (SABR) for metastatic unresected renal cell carcinoma (RCC) receiving immunotherapy (SAMURAI)</p>	<p>Determining whether the addition of stereotactic ablative radiotherapy (SABR) to the primary tumor in combination with immunotherapy improves outcomes compared to immunotherapy alone in patients with metastatic, unresected, renal cell carcinoma (RCC).</p>	<p>-Pathologically (histologically or cytologically) proven diagnosis of renal cell carcinoma that is node-positive unresectable (TxN1Mx) or metastatic (TxNxM1) based on history/physical examination or CT/MRI of the chest/abdomen/pelvis -Must have IMDC intermediate (1-2 factors) or poor risk disease -Measurable disease (node positive or metastatic) as defined by RECIST version 1.1 excluding the primary renal tumor. -Candidate for standard of care therapy with either IO-IO or IO-VEGF combination regimen. -Primary renal tumor measuring 20 cm or less in anterior to posterior dimension only on axial imaging -Adequate hematologic, renal, and hepatic function -Patient not recommended for or refused immediate cytoreductive nephrectomy or NOT planned for definitive treatment of all metastatic sites.</p>	<p>Study Coordinator: John Cherian (CTO) (john_cherian@med.unc.edu)</p>	<ul style="list-style-type: none"> • Vitals and labs on last day of RT EKG and PK lab if indicated.
<p>Westerman-NRG-GU014-CIRB: Randomized Phase II Trial of Pembrolizumab and Radiation vs Radiation and Concurrent Chemotherapy for High Grad T1 Bladder Cancer (PARRC TRIAL)</p>	<p>Randomized trial evaluating the safety and efficacy of chemoradiation versus radiation therapy and pembrolizumab</p>	<p>-Pathologically (histologically) proven diagnosis of T1 high-grade non-muscle invasive urothelial carcinoma of the bladder without radiographic evidence of regional nodal disease or metastatic disease (N0, M0) on CT, MRI, or PET/CT scan who would otherwise be treated with cystectomy off-trial.</p> <ul style="list-style-type: none"> • No pure squamous cell carcinoma or adenocarcinoma of the bladder. • No neuroendocrine (small or large cell) features. • No diffuse carcinoma in situ determined on cystoscopy and biopsy (i.e. extensive carcinoma in situ that is not just tumor-associated CIS in the opinion of the site investigator). 	<p>Study Coordinator: Catherine Griffin (CTO) (catherine_griffin@med.unc.edu, 984-974-8771, or epic inbasket)</p>	<ul style="list-style-type: none"> • N/A

Study and PI	Description	Enrollment Criteria	Who to contact	Nursing Duties
		<ul style="list-style-type: none"> No prostatic urethral involvement -No prior pelvic RT, systemic chemotherapy or immunotherapy for urothelial carcinoma, No prior treatment with anti-PD-1, anti PD-L1, anti PD-L2 or anti-CTLA4 antibody or any other antibody or drug targeting T-cell co-stimulation.		
Repka- NRG-GU015: The Phase III Adaptive Radiation and Chemotherapy for Muscle Invasive Bladder Cancer Trial (ARCHER)	Randomized trial comparing the effect of shorter term radiation (ultra-hypofractionated) therapy to the usual radiation therapy (hypofractionation) with standard of care chemotherapy, with cisplatin, gemcitabine or mitomycin and 5-fluorouracil for the treatment of patients with muscle invasive bladder cancer.	-Histologically proven, cT2-T3,N0M0 urothelial carcinoma of the bladder prior to randomization. * Note: Patients with mixed urothelial carcinoma will be eligible for the trial, but the presence of small cell carcinoma will make a patient ineligible -Must undergo a TURBT and radiological staging prior to randomization. -No diffuse carcinoma in situ (CIS) based on cystoscopy and biopsy, definitive clinical or radiologic evidence of metastatic disease, or prior pelvis radiation.	Study Coordinator: Erin Jennings (CTO) (erin_jennings@med.unc.edu or epic message)	<ul style="list-style-type: none"> N/A
Sud- SUD003/004: Correlative biomarker study of plasma circulating tumor HPV DNA as a minimally invasive biomarker disease status, treatment response, and surveillance in anal, penile, vulvar, and vaginal cancers	This study is a sub-study of the ETERNITY biorepository that aims to obtain biospecimens from 100 participants. The purpose of this study is to determine if ctHPV DNA has potential as a non-invasive biomarker to guide management and treatment monitoring of anal, vulvar, vaginal and penile cancer.	-Subject is planning or considering radiation therapy. -Subject must have undergone diagnostic procedure appropriate to the clinical situation, that documents disease status. -Subject must be willing to provide at least one of the following: <ul style="list-style-type: none"> Blood or extra tissue from previous or upcoming SOC biopsy or surgery Blood from a research-only visit. 	Study Coordinator: Chasity McCue (CTO) (chasity_mccue@med.unc.edu) Claire Kowalczyk (CTO) (Claire_Kowalczyk@med.unc.edu)	<ul style="list-style-type: none"> 2 Streck tubes of blood at pre-treatment, mid-treatment, end of treatment, and follow-up appointments

<u>Study and PI</u>	<u>Description</u>	<u>Enrollment Criteria</u>	<u>Who to contact</u>	<u>Nursing Duties</u>
<p>Sud- TISSUETOX: Circulating cell-free DNA for early detection of cancer therapy-related normal tissue injury</p>	<p>This study is a sub-study of the ETERNITY biorepository where we will be using blood samples from ETERNITY patients to try to identify biomarkers that can be used to detect early tissue injury in patients receiving cancer therapies.</p>	<p>- Those who are receiving RT to the thorax, abdomen, or who present to the cardio-oncology clinic for suspected cardio tox due to treatment</p>	<p>Study Coordinator: Chasity McCue (CTO) (chasity_mccue@med.unc.edu) Claire Kowalczyk (CTO) (Claire_Kowalczyk@med.unc.edu)</p>	<ul style="list-style-type: none"> • Blood draw at baseline, mid-rt, end of rt, and follow up
<p>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</p>	<p>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.</p>	<p>- 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.</p>	<p>Study Coordinator: Chasity McCue (CTO) (chasity_mccue@med.unc.edu) Erin Jennings (CTO) (erin_jennings@med.unc.edu or epic message)</p>	<ul style="list-style-type: none"> • Vitals at screening and follow up visits. • Occasional blood draw at a single time point-however will primarily use phlebotomy