

<u>Study and PI</u>	<u>Description</u>	<u>Enrollment Criteria</u>
<b>Head and Neck</b>		
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.	<ul style="list-style-type: none"> <li>-T0-T2 N2a-N3 M0 or T3-T4 N0-N3 M0 (AJCC 7<sup>th</sup> edition)</li> <li>-Biopsy proven SCC of the oropharynx or unknown primary</li> <li>-No prior history or therapy for the HPV+ HNSCC that makes them a candidate for this study</li> </ul>
Sheth: Clonidine HCl MBT vs. Placebo to Prevent Chemoradiotherapy-Induced Severe Oral Mucositis in Oropharyngeal Cancer. (VOICE)	Double-blinded placebo controlled oral mucositis prevention trial evaluating clonidine HCL vs. placebo in OPSCC patients receiving CRT	<ul style="list-style-type: none"> <li>-Patients with histologically or pathologically confirmed SCC of the oropharynx (including tonsils or the base of tongue) at one or several sites treated with surgical resection of their primary tumor for localized or locally advanced disease T ≥ T0 and/or N ≥ N1, M0 (AJCC 8<sup>th</sup> ed.)</li> <li>-Radiation plan must include delivery of a cumulative dose of 60-72 Gy with oropharynx receiving at least 50 Gy.</li> <li>-Eligible to receive a continuous course of external fractionated irradiation [conventional or intensity modulated radiation therapy (IMRT)] based on a daily dosing of 1.8 to 2.2 Gy/day 5 days/week in combination with cisplatin monotherapy either every 3 weeks (100 mg/m<sup>2</sup>) or weekly cisplatin (40 mg/m<sup>2</sup>)</li> </ul>
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	<ul style="list-style-type: none"> <li>-May be anti-PD1 naïve or anti-PD1 non-responders.</li> <li>-May have 1 or multiple mets, only 1 needs to be injectable and amenable to SBRT</li> </ul>

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<b>Breast</b>		
<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>	<ul style="list-style-type: none"> <li>-De novo invasive carcinoma of breast.</li> <li>-Pathological T1 (pT1) stage, Clinical or pathological N0, overall tumor Grade 1 or 2</li> <li>-ER/PR + (greater than or equal to 10% ER and PR by IHC staining)</li> <li>-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])</li> <li>-No pre- or post-operative systemic chemotherapy while on study or current ongoing treatment with anti-hormonal agents or hormonal replacement therapy</li> <li>-No synchronous bilateral breast cancer, Multifocal or multicentric tumor, or prior breast or thoracic radiation</li> </ul>
<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>	<ul style="list-style-type: none"> <li>-Patients with TNBC or HR+/HER2- BC</li> <li>- non-metastatic, T1*-T2 and N1-3</li> <li>- Primary breast tumor measuring ≥1.5 cm in maximal diameter</li> <li>- Breast-conserving surgery or mastectomy +/- reconstruction is planned following NAC</li> </ul>
<b>GYN</b>		
<p>Weiner- LCCC 2052: Patient related outcomes for gynecological radiation oncology (PRO-GRO)</p>	<p>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.</p>	<ul style="list-style-type: none"> <li>-Gynecologic cancer being treated by radiation at UNC</li> <li>-English speaking</li> <li>-Not a prisoner</li> </ul>

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<b>CNS</b>		
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
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.
<b>Peds/AYA</b>		
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

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<b>Metastatic</b>		
Casey: 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