# GU - PROSTATE

<table>
<thead>
<tr>
<th>Protocol Title</th>
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| RTOG 0534: A Phase III Trial Of Short Term Androgen Deprivation With Pelvic Lymph Node Or Prostate Bed Only Radiotherapy (SPORT) In Prostate Cancer Patients With A Rising PSA After Radical Prostatectomy | NCT00567580                    | • Adenocarcinoma of the prostate treated primarily with radical prostatectomy, pathologically proven to be lymph node negative by pelvic lymphadenectomy (N0) or lymph node status pathologically unknown  
  • Any type of radical prostatectomy will be permitted  
  • A post-radical prostatectomy entry PSA of 0.1 to 2.0 ng/mL at least 6 weeks after prostatectomy and within 30 days of entry;  
  • One of the following pathologic classifications: T3N0/Nx disease; or T2N0/Nx disease with positive prostatectomy margin and/or positive prostatic fossa or urethral-vesical anastomosis biopsies; or Prostatectomy Gleason score of 8 or less;  
  • PSA Doubling Time (PSADT) of > 6 months prior to registration |
| RTOG 0924: Androgen Deprivation Therapy and High Dose Radiotherapy With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial | NCT01368588                    | • Pathologically (histologically or cytologically) proven diagnosis of prostatic adenocarcinoma within 180 days of registration at moderate- to high-risk for recurrence as determined by one of the following combinations:  
  Gleason score 7-10 + T1c-T2b (palpation) + prostate-specific antigen (PSA) < 50 ng/mL (includes intermediate- and high-risk)  
  Gleason score 6 + T2c-T4 (palpation) or > 50% (positive) biopsies + PSA < 50 ng/mL  
  Gleason score 6 + T1c-T2b (palpation) + PSA > 20 ng/mL  
  • Patients with lymph nodes equivocal or questionable by imaging are eligible if the nodes are ≤ 1.5 cm  
  • No evidence of bone mets |
| RTOG 1115: Phase III Trial of Dose Escalated Radiation Therapy and Standard Androgen Deprivation Therapy (ADT) with a GnRH Agonist vs. Dose Escalated Radiation Therapy and Enhanced ADT with a GnRH Agonist and TAK-700 for Men with High Risk Prostate Cancer | NCT01546987                    | • Histologically confirmed diagnosis of adenocarcinoma of the prostate within 180 days prior to registration at high risk for recurrence as determined by one of the following combinations (risk group):  
  Gleason Score (GS) ≥ 9, PSA ≤ 150 ng/mL, any T stage  
  GS ≥ 8, PSA < 20 ng/mL, T stage ≥ T2  
  GS ≥ 8, PSA ≥ 20-150 ng/mL, any T stage  
  GS ≥ 7, PSA ≥ 20-150 ng/mL, any T stage  
  • Patients with lymph nodes equivocal or questionable by imaging are eligible if the nodes are < 2.0 cm  
  • No distant metastases (M0) on bone scan within 90 days prior to registration  
  • Any patient undergoing brachytherapy must have transrectal ultrasound confirmation of prostate volume < 60 cc |

# GI - PANCREAS

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| RTOG 0848: A Phase III Trial Evaluating Both Erlotinib and Chemoradiation as Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma | NCT01013649                    | • Histologic proof of primary head of pancreas invasive adenocarcinoma managed with a potentially curative resection (i.e., removal of all gross tumor) involving a classic pancreaticoduodenectomy (Whipple) or a pylorus preserving pancreaticoduodenectomy.  
  • Patients with invasive adenocarcinoma that also contains a component of intraductal papillary mucinous neoplasm (IPMN) are eligible  
  • Patients will be staged according to the 6th edition AJCC staging system with pathologic stage T1-3, N0-1, M-0 being eligible.  
  • Patients managed with a total pancreatectomy, a distal pancreatectomy, or central pancreatectomy are excluded |
# Clinical Trials Office

### Breast

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| RTOG 1005: A Phase III Trial Of Accelerated Whole Breast Irradiation With Hypofractionation Plus Concurrent Boost Versus Standard Whole Breast Irradiation Plus Sequential Boost For Early-Stage Breast Cancer | NCT01349322                    | • Pathologically proven diagnosis of breast cancer resected by lumpectomy and whole-breast irradiation (WBI) with boost without regional nodal irradiation planned  
  • Must meet one of the following criteria:  
    Stage I or II breast cancer AND at least one of the following:  
    - Age < 50 years  
    - Lymphovascular space invasion (LVI)  
    - Focally positive resection margins  
    - Grade III histology  
    - Non-hormone-sensitive breast cancer (estrogen-receptor negative (ER-) and progesterone-receptor (PR-) negative)  
  • Stage 0 breast cancer with nuclear grade 3 ductal carcinoma in situ (DCIS) and patient age < 50 years  
  • No DCIS and age > 50 years  
  • No DCIS and age < 50 years and nuclear grade 1 or 2  
  • Breast-conserving surgery with margins defined as follows:  
    - Negative margins defined as no tumor at the resected specimen edge  
    - Close resection margins > 0 mm to ≤ 2 mm as follows:  
      - One close resection margin and EIC  
      - Two or more close resection margins  
    - A locally positive resection margin |

### Gyn Onc - Cervix

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| UCSD: International Evaluation of Radiotherapy Technology Effectiveness in Cervical Cancer (INTERTECC): Phase II/III Clinical Trial of Intensity Modulated Radiation Therapy with Concurrent Cisplatin For Stage I-IVA Cervical Carcinoma | NCT01554397                    | • Biopsy-proven, invasive primary squamous cell carcinoma, adenocarcinoma, or adenosquamous carcinoma of the cervix within 60 days  
  • FIGO clinical stage I-IVA cervical cancer  
  • No prior radiation therapy to the pelvis or abdomen that would result in overlap of radiation therapy fields |
| UCSD: A Phase I Trial of Intensity Modulated Radiation Therapy with Concurrent Cisplatin and Escalating Gemcitabine For Locally Advanced Cervical Carcinoma | NCT01554410                    | • FIGO stage IIB-IVA locally advanced carcinoma of the uterine cervix or stage I with biopsy-proven pelvic node metastases, positive surgical margins, or parametrial extension, excluding patients with para-aortic lymphadenopathy. Approximately 18 patients are expected to be accrued at the Moores Cancer Center  
  • No Evidence of para-aortic lymphadenopathy or distant metastases |
| RTOG 0724: Phase II Randomized Study of Concurrent Chemotherapy and Pelvic Radiation Therapy w/ or w/o Adjuvant Chemotherapy in High-Risk Patients with Early-Stage Cervical Carcinoma Following Radical Hysterectomy | NCT00980954                    | • Patients must have undergone radical hysterectomy (open, laparoscopically or robotic) and staging including both para-aortic and pelvic node sampling for cervical carcinoma within 70 days prior to study entry.  
  • Patients with clinical stage IA2, IB or IIA squamous, adenosquamous, or adenocarcinoma of the cervix who have any/all of the following high-risk features after surgery:  
    - Positive pelvic nodes, Positive parametrium, Positive para-aortic nodes- completely resected, PET/CT negative (PET only required if positive para-aortic nodes during surgery)  
    - No distant metastases[NOTE: Patients with positive para-aortic nodes- completely resected, PET/CT negative are eligible] |

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## BRAIN

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| RTOG 1270: A Phase III Trial of Post-Surgical Stereotactic Radiosurgery (SRS) Compared with Whole Brain Radiotherapy (WBRT) for Resected Metastatic Brain Disease | NCT00377156                     | • Four or fewer brain metastases (as defined on the pre-operative MRI brain scan) and status post resection of one of the lesions.  
• Pathology from the resected brain metastasis must be consistent with a non-central nervous system primary site.  
NOTE: Patients with or without active disease outside the nervous system are eligible (including patients with unknown primaries), as long as the pathology from the brain is consistent with a non-central nervous system primary site.  
• Any unresected lesions must measure <3.0 cm in maximal extent on the contrasted pre-operative treatment MRI brain scan obtained <35 days prior to pre-registration. The unresected lesions will be treated with SRS as outlined in the treatment section (Section 7.0) of the protocol. NOTE: The metastases size restriction does not apply to the resected brain metastasis; with resected brain metastases only surgical cavity size determines eligibility (see 3.114).  
• Resection cavity must measure <5.0 cm in maximal extent on the post-operative MRI (or CT) brain scan obtained <35 days prior to pre-registration. NOTE: It is permissible for the resection of a dominant brain metastasis to include a smaller “satellite” metastasis as long as the single resection cavity is less than the maximum size requirements.  
• All standard tumor-staging procedures necessary to define baseline extracranial disease status completed <42 days prior to pre-registration.  
• Ability to be treated with either a gamma knife or a linear accelerator-based radiosurgery system. |
| RTOG 0929: A Randomized Phase I/II Study of ABT-888 in Combination with Temozolomide in Recurrent (Temozolomide Resistant) Glioblastoma | NCT01026493                     | • Histologically proven intracranial glioblastoma or gliosarcoma. There must be imaging confirmation of tumor progression or regrowth.  
• Patients must have completed at least 2 adjuvant cycles of temozolomide.  
• No more than 2 prior regimens for recurrent disease for glioblastoma/gliosarcoma.  
• If patient has seizures, they must be clinically controlled.  
• Must be able to swallow oral medications.                                                                                                                                                                                                                                                                                                                                                                      |
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**CLINICAL TRIALS OFFICE**

### HEAD & NECK

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| RTOG 0920 | A Phase III Study of Postoperative Radiation Therapy (IMRT) +/- Cetuximab for Locally-Advanced Head and Neck Cancer | NCT00956087 | - Pathologically proven diagnosis of squamous cell carcinoma (including variants such as verrucous carcinoma, spindle cell carcinoma, carcinoma NOS, etc.) of the head/neck (oral cavity, oropharynx or larynx); Note: Hypopharynx primaries are excluded.
- Clinical stage T1, N1-2 or T2-3, N0-2, M0 including no distant metastases
- Gross total resection of the primary tumor with curative intent must be completed within 7 weeks of registration with surgical pathology demonstrating one or more of the following "intermediate" risk factors: (Perineural invasion; Lymphovascular invasion; Single lymph node > 3 cm or = 2 lymph nodes [all < 6 cm] [no extracapsular extension]; Close margin[s] of resection, defined as cancer extending to within 5 mm of a surgical margin; T3 or microscopic T4a primary tumor (Note: Gross T4a or T4b is ineligible); T2 oral cavity cancer with > 5 mm depth of invasion)
- Patients with simultaneous primaries or bilateral tumors are excluded.
- Per the operative report, positive margin(s) [defined as tumor present at the cut or inked edge of the tumor], nodal extracapsular extension, and/or gross residual disease after surgery are excluded. |

| RTOG 1008 | A Randomized Phase II Study of Adjuvant Concurrent Radiation and Chemotherapy Versus Radiation Alone in Resected High-Risk Malignant Salivary Gland Tumors | NCT01220583 | - Pathologically proven diagnosis of a malignant major salivary gland tumor of the following histologic subtypes: high grade mucoepidermoid carcinoma, salivary duct carcinoma or high grade adenocarcinoma;
- Surgical resection with curative intent within 8 weeks prior to registration;
- Pathologic stage T3-4 or N1-3 or T1-2, N0 with a close (=1mm) or microscopically positive surgical margin (AJCC, 7th ed.); patients must be free of distant metastases based upon the following minimum diagnostic workup: history/physical and radiologic confirmation
- Patients with residual macroscopic disease after surgery are excluded;
- Patients with salivary gland malignancies originating from the minor salivary glands are excluded;
- Patients with histologies other than high grade: mucoepidermoid carcinoma, adenocarcinoma or salivary duct carcinoma are excluded |

| RTOG 1016 | A Phase III Trial of Radiotherapy plus Cetuximab versus Chemoradiotherapy in HPV-Associated Oropharynx Cancer | NCT01302834 | - Pathologically (histologically or cytologically) proven diagnosis of squamous cell carcinoma of the oropharynx (tonsil, base of tongue, soft palate, or oropharyngeal walls); Note: Paraffin-embedded cytology specimens are acceptable for p16 evaluation
- Patients must be positive for p16
- Patients must have clinically or radiographically evident measurable disease at the primary site or at nodal stations. Tonsillectomy or local excision of the primary without removal of nodal disease is permitted, as is excision removing gross nodal disease but with intact primary site. Fine needle aspirations of the neck are insufficient due to limited tissue for retrospective central review. Biopsy specimens from the primary or nodes measuring at least 3-5 mm are required.
- Clinical stage T1-2, N2a-N3 or T3-4, any N (AJCC, 7th ed.), including no distant metastases, based upon the following minimum diagnostic workup: history/physical by rad onc and ENT/H&N Surgeon and radiologic confirmation |

| GENELUX GLONC-1 005 | Phase I clinical trial of intravenous genetically modified Vaccinia virus (GL-ONC1) with concurrent Cisplatin and radiotherapy for locoregionally advanced head and neck carcinoma | NCT01584284 | - Confirmed diagnosis of histologically or cytologically documented Stage III to IVB primary, non-metastatic head and neck cancer for newly diagnosed patients with no prior disease-related treatment (e.g., chemotherapy, radiation treatment, surgery, etc.).
- Stage III-IVB disease |

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