### Biology

**LLUCC-BIOSPECIMEN LABORATORY - SPECIMEN COLLECTION**

Loma Linda University Cancer Center Biospecimen Laboratory Specimen Collection Protocol

**Mark E. Reeves, MD, PhD**

### Brain

**SWOG-NRG-BN001**

Randomized Phase II Trial of Hypofractionated Dose-Escalated Photon IMRT or Proton Beam Therapy Versus Conventional Photon Irradiation With Concomitant and Adjuvant Temozolomide in Patients With Newly Diagnosed Glioblastoma

[https://clinicaltrials.gov/ct2/show/NCT02179086](https://clinicaltrials.gov/ct2/show/NCT02179086)

**Joseph Kang, MD**

**SWOG-A221101**

A Phase III Randomized, Double-Blind Placebo Controlled Study of Armodafinil (Nuvigil®) To Reduce Cancer-Related Fatigue in Patients with High Grade Glioma

[https://clinicaltrials.gov/ct2/show/NCT01781468](https://clinicaltrials.gov/ct2/show/NCT01781468)

**Muhammad Kamal, MD**

### Breast

**NSABP-B51**

A Randomized Phase III Clinical Trial Evaluating Post-Mastectomy Chest Wall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy

[https://clinicaltrials.gov/ct2/show/NCT01872975](https://clinicaltrials.gov/ct2/show/NCT01872975)

**Sharon Lum, MD**

**SWOG-A011106**

ALTERNate approaches for clinical stage II or III Estrogen Receptor positive breast cancer NeoAdjuvant TrEatment (ALTERNATE) in postmenopausal women: A Phase III Study

[https://clinicaltrials.gov/ct2/show/NCT01953588](https://clinicaltrials.gov/ct2/show/NCT01953588)

**Gayathri Nagaraj, MD**

**SWOG-A011202**

A Randomized Phase III Trial Comparing Axillary Lymph Node Dissection to Axillary Radiation in Breast Cancer Patients (cT1-3 N1) Who Have Positive Sentinel Lymph Node Disease After Neoadjuvant Chemotherapy

[https://clinicaltrials.gov/ct2/show/NCT01901094](https://clinicaltrials.gov/ct2/show/NCT01901094)

**Sharon Lum, MD**

**SWOG-S1207**

Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of EVEROLIMUS in Patients with High-Risk Hormone Receptor-Positive and HER2/neu Negative Breast Cancer


**Gayathri Nagaraj, MD**

**YALE University-SHAVE2**

A Multicenter Randomized Controlled Trial of Routine Shave Margins vs. Standard Partial Mastectomy in Breast Cancer Patients

[https://clinicaltrials.gov/ct2/show/NCT02772731](https://clinicaltrials.gov/ct2/show/NCT02772731)

**Sharon Lum, MD**

**Merck-MK3475-355**

A Randomized, Double-Blind, Phase III Study of pembrolizumab (MK-3475) plus Chemotherapy vs Placebo plus Chemotherapy for Previously Untreated Locally Recurrent Inoperable or Metastatic Triple Negative Breast Cancer-(KEYNOTE-355)

[https://clinicaltrials.gov/ct2/show/NCT02819518](https://clinicaltrials.gov/ct2/show/NCT02819518)

**Gayathri Nagaraj, MD**

**08/01/2017**
### Breast continued

<table>
<thead>
<tr>
<th>Investigator Initiated GRASP-CIPN</th>
<th>A Pilot Study of Intraneural Facilitation for Managing Chemotherapy-Induced Peripheral Neuropathy</th>
<th>Gayathri Nagaraj, MD</th>
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### GI

#### Bowel

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<tr>
<th>SWOG-S1316</th>
<th>Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction</th>
<th>Maheswari Senthil, MD</th>
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### Colon

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<tr>
<th>SWOG-S0820</th>
<th>A Double Blind Placebo-Controlled Trial of Efornithine and Sulindac to Prevent Recurrence of High Risk Adenomas and Second Primary Colorectal Cancers in Patients with Stage 0-III Colon Cancer, Phase III - Preventing Adenomas of the Colon with Efornithine and Sulindac (PACES)</th>
<th>Chung-Tsen Hsueh, MD, PhD</th>
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### Esophagus

<table>
<thead>
<tr>
<th>Radiation Medicine</th>
<th>A phase II trial of proton-chemotherapy (PCT) for resectable esophageal or esophagogastric junction cancer</th>
<th>Gary Yang, MD</th>
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### Gastric

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<tr>
<th>Investigator Initiated HIPEC</th>
<th>Adjuvant Hyperthermic Intraperitoneal Chemotherapy for Locally Advanced Gastric Cancer</th>
<th>Maheswari Senthil, MD</th>
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### Liver

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<tr>
<th>Radiation Medicine</th>
<th>Randomized controlled trial of transarterial chemoembolization versus proton beam radiotherapy for the treatment of hepatocellular carcinoma</th>
<th>David Bush, MD &amp; Michael De Vera, MD</th>
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<th>Radiation Medicine</th>
<th>Phase I/II Trial of Stereotactic Body Proton Therapy (SBPT) for Patients with Liver Metastases</th>
<th>Gary Yang, MD</th>
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### Pancreas

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<tr>
<th>Radiation Medicine</th>
<th>A phase II trial of gemcitabine and erlotinib (GB) plus proton-chemotherapy (PCT) and capox for locally advanced pancreatic cancer (LAPC)</th>
<th>Gary Yang, MD</th>
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**GU**

**Bladder**

SWOG-S1314  
A Randomized Phase II Study of Co-Expression Extrapolation (COXEN) With Neoadjuvant Chemotherapy for Localized, Muscle-Invasive Bladder Cancer  
[https://clinicaltrials.gov/ct2/show/NCT02177695](https://clinicaltrials.gov/ct2/show/NCT02177695)  
John Wong, MD

Merck-MK3475-361  
A Phase III Randomized, Controlled Clinical Trial of Pembrolizumab with or without Platinum-Based Combination Chemotherapy versus Chemotherapy in Subjects with Advanced or Metastatic Urothelial Carcinoma  
[https://clinicaltrials.gov/ct2/show/NCT02853305](https://clinicaltrials.gov/ct2/show/NCT02853305)  
John Wong, MD

**GU**

**Prostate**

Radiation Medicine  
Phase I-II trial of hypofractionated conformal proton beam radiation therapy for favorable-risk prostate cancer  
[https://clinicaltrials.gov/ct2/show/NCT00831623](https://clinicaltrials.gov/ct2/show/NCT00831623)  
Jerry Slater, MD

Radiation Medicine  
Cytogenetic damage as a biomarker of radiation sensitivity in prostate cancer  
Marcelo Vazquez, MD, PhD

**Testicular**

Investigator Initiated-4T-14-1  
Phase II Trials of Retroperitoneal Lymph Node Dissection as First-Line Treatment for Testicular Seminoma with Isolated Retroperitoneal Disease (1-2cm)  
[https://clinicaltrials.gov/ct2/show/NCT02537548](https://clinicaltrials.gov/ct2/show/NCT02537548)  
Brian Hu, MD

**GYN**

**Ovarian**

Investigator Initiated HIPEC  
Hyperthermic Intraperitoneal Chemotherapy for Recurrent Ovarian Cancer  
[https://clinicaltrials.gov/ct2/show/NCT02672098](https://clinicaltrials.gov/ct2/show/NCT02672098)  
Mazdak Momeni, MD

**Uterus**

GOG-0263  
Randomized Phase III Clinical Trial of Adjuvant Radiation Versus Chemoradiation in Intermediate Risk, Stage I/IIA Cervical Cancer Treated with Initial Radical Hysterectomy and Pelvic Lymphadenectomy  
[https://clinicaltrials.gov/ct2/show/NCT01101451](https://clinicaltrials.gov/ct2/show/NCT01101451)  
Yevgeniya Ioffe, MD
Leukemia

SWOG-S1318  A Phase II Study of Blinatumomab (NSC-765986) and POMP (Prednisone, Vincristine, Methotrexate, 6-Mercaptopurine) for Patients ≥ 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Negative (Ph-) Acute Lymphoblastic Leukemia (ALL) and of Dasatinib (NSC-732517), Prednisone and Blinatumomab for Patients ≥ 65 Years of Age with Newly Diagnosed Philadelphia-Chromosome Positive (Ph+) ALL, Relapsed/Refractory Philadelphia-Chromosome Positive (+) ALL, and Philadelphia-Chromosome-Like Signature (Ph-Like) ALL (Newly Diagnosed or Relapsed/Refractory) with Known or Presumed Activating Dasatinib-Sensitive Mutations or Kinase Fusions (DSMKF)
https://clinicaltrials.gov/ct2/show/NCT02143414

Muhammad Kamal, MD

Lung

Novartis-CLDK378A2112  A multi-center, randomized open label study to assess the systemic exposure, efficacy, and safety of 450 mg ceritinib taken with a low-fat meal and 600 mg ceritinib taken with a low-fat meal as compared with that of 750 mg ceritinib taken in the fasted state in adult patients with ALK rearranged (ALK-positive) metastatic non-small cell lung cancer (NSCLC)
https://clinicaltrials.gov/ct2/show/NCT02299505

Hamid Mirshahidi, MD

SWOG-A151216  Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST)
https://clinicaltrials.gov/ct2/show/NCT02194738

Hamid Mirshahidi, MD

SWOG-A081105  Randomized Double Blind Placebo Controlled Study of Erlotinib or Placebo in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-small Cell Lung Cancer (NSCLC)
https://clinicaltrials.gov/ct2/show/NCT02194738

Hamid Mirshahidi, MD

SWOG-EA5142  Adjuvant Nivolumab in Resected Lung Cancers (ANVIL) A Randomized Phase III Study of Nivolumab After Surgical Resection and Adjuvant Chemotherapy in Non-Small Cell Lung Cancers
https://clinicaltrials.gov/ct2/show/NCT02595944

Hamid Mirshahidi, MD

SWOG-E4512  A Phase III Double-Blind Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib versus Placebo for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein
https://clinicaltrials.gov/ct2/show/NCT02201992

Hamid Mirshahidi, MD

SWOG-S1400  Phase II/III Biomarker-Driven Master Protocol for Second Line Therapy of Squamous Cell Lung Cancer
http://clinicaltrials.gov/ct2/show/NCT02154490

Hamid Mirshahidi, MD

Mirati – 265-109  Phase 2, Parallel-Arm Study of MGCD265 in Patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer with Activating Genetic Alterations in Mesenchymal-Epithelial Transition Factor
https://clinicaltrials.gov/ct2/show/NCT02544633

Hamid Mirshahidi, MD
**Lung continued**

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<tr>
<td>SWOG-S1507</td>
<td>A Phase II Trial of Trametinib with Docetaxel in Patients with KRAS Mutation Positive Non-Small Cell Lung Cancer (NSCLC) and Progressive Disease Following One or Two Prior Systemic Therapies</td>
<td>Hamid Mirshahidi, MD</td>
<td><a href="https://clinicaltrials.gov/ct2/show/NCT02642042">NCT02642042</a></td>
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<td>PharmaMar-PM1183-C-003-14</td>
<td>Phase III Randomized Clinical Trial of Lurbinectedin (PM01183) plus Doxorubicin (DOX) versus Topotecan as Treatment in Patients with Small-Cell Lung Cancer (SCLC) Who Failed One Prior Platinum-containing Line (ATLANTIS Trial)</td>
<td>Hamid Mirshahidi, MD</td>
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**Multiple**

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<td>SWOG-EAY131-MATCH</td>
<td>Molecular Analysis for Therapy Choice (MATCH)</td>
<td>Gayathri Nagaraj, MD</td>
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<td>SWOG-S1609</td>
<td>DART: Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare Tumors</td>
<td>John Wong, MD</td>
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**Soft Tissue Sarcoma**

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<td>Radiation Medicine</td>
<td>A phase II study of preoperative proton therapy in soft tissue sarcomas of the extremities and body wall</td>
<td>Gary Yang, MD</td>
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**Registry**

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<td>Radiation Medicine</td>
<td>Radiation Medicine Patient Registry</td>
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