

# Active Protocols

**Note: Click on the protocol title to view the eligibility requirements.**

*Type of Cancer*      *Breast (DCIS)*

<i>Protocol Title</i>	<i>Protocol Name</i>	<i>Sponsor</i>	<i>Munster Investigator</i>
NSABP B-43	A Phase III Clinical Trial Comparing Trastuzumab Given Concurrently with Radiation Therapy and Radiation Therapy Alone for Women with HER2 Positive Ductal Carcinoma In-Situ Resected by Lumpectomy	NSABP	Robin, Kozloff, Fuller, Wallace, Mishoulam, Kassar

*Type of Cancer*      *Breast*

<i>Protocol Title</i>	<i>Protocol Name</i>	<i>Sponsor</i>	<i>Munster Investigator</i>
ACOSOG Z1031	A Randomized Phase III Trial Comparing 16 to 18 Weeks of Neoadjuvant Exemestane (25mg daily), Letrozole (2.5mg), or Anastrozole (1mg) in Postmenopausal Women with Clinical Stage II and III Estrogen Receptor Positive Breast Cancer	CTSU	Robin, Kozloff, Fuller, Wallace, Mishoulam, Kassar
CTSU ECOG E5103	A Double-Blind Phase III Trial of Doxorubicin and Cyclophosphamide followed by Paclitaxel with Bevacizumab or Placebo in Patients with Lymph Node Positive and High Risk Lymph Node Negative Breast cancer	CTSU	Robin, Fuller, Kassar Kozloff, Mishoulam, Wallace
CTSU ISBG 24-02 BIG (SOFT)	A Phase III Trial Evaluating the Role of Ovarian Function Suppression and the Role of Exemestane Adjuvant Therapies for Premenopausal Women with Endocrine Responsive Breast Cancer	CTSU	Robin, Fuller, Kassar, Kozloff, Mishoulam, Wallace
<a href="#">NSABP B-40</a>	A Randomized Phase III Trial of Neoadjuvant Chemotherapy in Patients with Palpable and Operable Breast Cancer Evaluating the Effect on Pathologic Complete Response (pCR) of Adding Capecitabine or Gemcitabine to Docetaxel when Administered Following AC and Correlative Sciences Studies Attempting to Identify Predictors of High Likelihood for pCR with Each of the Regimens	NSABP	Robin, Mishoulam, Kozloff Fuller, Morgan-Ihrig
NSABP B-46I	A Phase III Clinical Trial Comparing the Combination of TC Plus Bevacizumab to TAC for Women with Node-Positive or High Risk Node-Negative Breast Cancer	NSABP	Robin, Fuller, Kozloff Mishoulam, Kassar, Wallace

SWOG S0221	A Phase III Trial of Continuous Schedule AC + G Vs. Q 2 week Schedule AC, Followed by Paclitaxel Given Either Every 2 Weeks or Weekly for 12 Weeks as Post-Operative Adjuvant Therapy in Node-Positive or High Risk Node-Negative Breast Cancer	CTSU	Robin, Kozloff, Fuller, Wallace, Mishoulam, Kassar
<a href="#">TAILORx (PACCT-1)</a> - <a href="#">Press Release</a> - <a href="#">Brochure</a>	Program for the Assessment of Clinical Cancer Tests (PACCT-1): Trial Assigning Individualized Options for Treatment: TAILORx Trial	CTSU	Robin, Mishoulam, Kozloff, Fuller,
Wyeth 3144A2-3004	A Randomized Double-Blind Placebo-Controlled Trial of Neratinib (HKI-272) After Trastuzumab in Women with Early-Stage HER-2/NEU Overexpressed/Amplified Breast Cancer	Pfizer	Robin, Fuller, Kozloff Mishoulam, Kassar Wallace

**Type of Cancer**      *Breast (Metastatic)*

<b>Protocol Title</b>	<b>Protocol Name</b>	<b>Sponsor</b>	<b>Munster Investigator</b>
Genentech TOC4129g_ W020698 (CLEOPATRA)	A Randomized, Double-Blind, Placebo Controlled Clinical Trial to Evaluate the Efficacy and Safety of Pertuzumab + Trastuzumab+Docetaxel vs. Trastuzumab +Docetaxel in Previously Untreated HER2-Positive Metastatic Breast Cancer	Genentech	Robin, Fuller, Kassar, Kozloff, Mishoulam, Wallace
Wyeth 3144A2-3003-WW	A Phase 3 Randomized Open Label Study of Neratinib Versus Lapatinib and Capecitabine for the Treatment of ErbB-2 Locally Advanced or Metastatic Breast Cancer	Wyeth	Robin, Kozloff, Fuller, Wallace, Mishoulam, Kassar

**Type of Cancer**      *Colon (Metastatic)*

<b>Protocol Title</b>	<b>Protocol Name</b>	<b>Sponsor</b>	<b>Munster Investigator</b>
<a href="#">CTSU CALGB/SWOG 80405</a>	A Phase III Trial of Irinotecan/5-FU/Leucovorin or Oxaliplatin/5FU/Leucovorin with Bevacizumab	CTSU	Robin, Mishoulam, Fuller, Kozloff
VELOUR	A Multinational, Randomized, Double-blind Study, Comparing the Efficacy of Afibercept Once Every 2 Weeks Versus Placebo in Patients With Metastatic Colorectal Cancer (MCRC) Treated with Irinotecan/5-FU Combination (FOLFIRI) After Failure of an Oxiplatin Based Regimen	Sanofi Aventis	Robin, Kozloff, Fuller Wallace, Mishoulam Kassar

**Type of Cancer**      *Hodgkin Lymphoma*

**Protocol Title**  
[SWOG S0816](#)

**Protocol Name**  
A Phase II Trial of Response Adapted Therapy of Stage III-IV Hodgkin Lymphoma Using Early Interim FDG-PET Imaging

**Sponsor**  
CTSU

**Munster Investigator**  
Robin, Fuller, Kassar  
Kozloff, Mishoulam,

**Type of Cancer**      *Lung (Non-Small Cell, Adjuvant)*

**Protocol Title**

**Protocol Name**

**Sponsor**

**Munster Investigator**

CALGB 30506

A Randomized Phase III Trial to Evaluate the Capacity of a Genomic Prognostic Model to Identify Stage I NSCLC Patients as Candidates for Adjuvant Chemotherapy

CTSU

Robin, Kozloff, Fuller  
Wallace, Mishoulam  
Kassar

MAGRIT

MAGE-A3 as Adjuvant Non-Small Cell Lung Cancer Immunotherapy

GlaxoSmithKline

Robin

CTSU ECOG 1505

A Phase III Randomized Trial of Adjuvant Chemotherapy With or Without Bevacizumab for Patients in Second or Subsequent Remission or in Remission After Primary Induction Failure

CTSU

Robin, Mishoulam, Kozloff, Fuller

**Type of Cancer**      *Lymphoma*

**Protocol Title**

**Protocol Name**

**Sponsor**

**Munster Investigator**

[CTSU CALGB 50303](#)

Phase III Study of R-Chop v. Dose-Adjusted Epoch R With Molecular Profiling in Untreated De Novo Diffuse Large B-Cell Lymphomas

CTSU

Robin

**Type of Cancer**      *Multiple Myeloma*

**Protocol Title**

**Protocol Name**

**Sponsor**

**Munster Investigator**

CTSU E1A06

An Intergroup Phase III Randomized Controlled Trial Comparing Melphalan, Prednisone and Thalidomide (MPT) versus Melphalan, Prednisone and Lenalidomide (Revlimid) (MPR) in Newly Diagnosed Multiple Myeloma Patients Who are Not Candidates for High Dose Therapy

CTSU

Robin, Fuller, Kassar  
Kozloff, Mishoulam,  
Wallace

CTSU S0777

A Randomized Phase II Trial of CC-5013 (Lenalidomide, NSC-703813) and Low Dose Dexamethasone (LLD) Versu Bortezomib (PS-341, NSC-681239), Lenalidomide and Low Dose Dexamethasone (BLLD) for Induction in Patients with Previously Untreated Multiple Myeloma without Intent for Immediate Stem Cell Transplant

CTSU

Robin, Fuller, Kassar  
Kozloff, Mishoulam  
Wallace

*Type of Cancer*      *Ovarian*

***Protocol Title***

CTSU GOG  
0213

***Protocol Name***

A Phase III Randomized Controlled Clinical Trial of Carboplatin and Paclitaxel Alone or in Combination with Bevacizumab (NSC #704865, IND #7921) Followed by Bevacizumab and Secondary Cytoreductive Surgery in Platinum-Sensitive, Recurrent Ovarian, Peritoneal primary and Fallopian Tube Cancer

***Sponsor***

CTSU

***Munster Investigator***

Robin, Fuller, Kassar,  
Kozloff, Mishoulam,  
Wallace

*Type of Cancer*      *Prostate Cancer (Metastatic)*

***Protocol Title***

SWOG S0421

***Protocol Name***

Phase III Study of Docetaxel and Astrasentan versus Docetaxel and Placebo for Patients with Advanced Hormone Refractory Prostate Cancer

***Sponsor***

CTSU

***Munster Investigator***

Robin, Kozloff, Fuller  
Wallace, Mishoulam

*Type of Cancer*      *Rectal*

***Protocol Title***

[NSABP R-04](#)

***Protocol Name***

A Clinical Trial Comparing Peroperative Radiation Therapy and Capecitabine with Preoperative Radiation Therapy and Continuous Intravenous Infusion (CVI) of 5-fluorouracil (5-FU) in the Treatment of Patients with Operable Carcinoma of the Rectum

***Sponsor***

NSABP

***Munster Investigator***

Robin, Mishoulam, Kozloff, Fuller, Zajac, Bryant

*Type of Cancer*      *Renal Cell*

***Protocol Title***

CTSU E2805

***Protocol Name***

Adjuvant Sorafenib or Sunitinib for Unfavorable Renal Carcinoma

***Sponsor***

CTSU

***Munster Investigator***

Robin, Mishoulam, Kozloff

*Other Miscellaneous Studies*

***Protocol Title***

BNK 09-138

***Protocol Name***

A Biological Sample Collection protocol of patients with and without Solid Organ Malignancies

***Sponsor***

Hoosier Oncology  
Group (HOG)

***Munster Investigator***

Robin, Fuller, Kassar  
Kozloff, Mishoulam,

[NOPR PET Registry](#)

NOPR PET Registry

Academy of  
Molecular Imaging

Ali, Barai, Bijal, Dempsey, Howard, Jano, Klein, Kozloff,  
Legaspi, Mishoulam, Modur, Patel, Pellar, Rawlings, Robin,  
Shabeeb, Shah, Waldron