

**Fort Wayne Medical Oncology and Hematology Open Protocol List  
11-1-11**

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**BREAST**

**NEOADJUVANT**

Breast	40601	CALGB	Randomized Phase III Trial of Paclitaxel Combined with Trastuzumab, Lapatinib, or Both As Neoadjuvant Treatment of HER-2 Positive Primary Breast Cancer
Breast	40603	CALGB	Randomized Phase II 2x2 Factorial Trial of the Addition of Carboplatin +/- Bevacizumab To Neoadjuvant Weekly Paclitaxel Followed by Dose Dense AC in Hormone Receptor-poor Her2-Negative Breast Cancer
<b>Temp. Suspension as of 11-10-11</b>			
Breast	S0800	SWOG	A Randomized Phase II Trial of Weekly Nanoparticle Albumin Bound Paclitaxel (Nab-Paclitaxel) (NSC-736631) With or Without Bevacizumab, Either Preceded by or Followed By Q 2 Week Doxorubicin (A) and Cyclophosphamide (C) Plus Pegfilgrastim (PEG-G) As Neoadjuvant Therapy for Inflammatory and Locally Advanced Her-2/Neu Negative Breast Cancer

**ADJUVANT**

Breast	BRE09-146	HOG	PARP Inhibition after Preoperative Chemotherapy in Patients with Triple Negative Breast Cancer or ER/PR +, HER2 negative with known BRCA1/2 Mutations
Breast	B-47	CTSU	A Randomized Phase III trial of Adjuvant Therapy Comparing Chemotherapy Alone (Six cycles of Docetaxel Plus Cyclophosphamide or Four Cycles of Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel) to Chemotherapy plus Trastuzumab in Women With Node-Positive or High-Risk Node-Negative HER2-Low Invasive Breast Cancer
Breast	S1007	CTSU	A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy In Patients with 1-3 Positive Nodes, Hormone Receptor-Positive and HER2-Negative Breast Cancer With Recurrence Score (RS) of 25 or Less

**METASTATIC**

Breast	40502	CALGB	A Randomized Phase III Trial of Weekly Paclitaxel Compared to Weekly Nanoparticle Albumin Bound Nab-Paclitaxel or Ixabepilone Combined with Bevacizumab As First Line Therapy for Locally Recurrent Or Metastatic Breast Cancer
<b>ARM C CLOSED</b>			
Breast	N0733	CTSU	Phase II Trial of Capecitabine and Lapatinib with or without IMC-A12 in Patients with HER2 Positive Breast Cancer Previously Treated with Trastuzumab and an Anthracycline and/or a Taxane
Breast	40503	CALGB	Endocrine Therapy in Combination with Anti-VEGF Therapy: A Randomized, Double-Blind, Placebo-Controlled Phase III Trial of Endocrine Therapy Alone or Endocrine Therapy plus Bevacizumab for Women with Hormone Receptor-Positive Advanced Breast Cancer

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**CANCER CONTROL AND HEALTH OUTCOME**

Zoledronic Acid	70604	CALGB	A Randomized, Phase III Study of Standard Dosing Versus Longer Dosing Interval of Zoledronic Acid in Metastatic Cancer
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**GASTROINTESTINAL**

Colon	80702	CALGB	A Phase III Trial of 6 versus 12 Treatments of Adjuvant FOLFOX plus Celecoxib or Placebo For Patients with Resected Stage III Colon Cancer
Colon or Rectum	80405	CALGB	A Phase III Trial of Irinotecan/5-FU/Leucovorin or Oxaliplatin/5-FU/Leucovorin with Bevacizumab or Cetuximab (C225) for Patients with Untreated Metastatic Adenocarcinoma of the Colon or Rectum
<b>*Combination of Bev/Cetuximab Arm 3 CLOSED*</b>			
Hepatocellular	80802	CALGB	Phase III Randomized study of Sorafenib plus Doxorubicin versus Sorafenib in Patients with Advanced Hepatocellular Carcinoma

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Pancreatic 09-068-B	Phase II	A Multi-Center, Double-Blind, Placebo-Controlled, Randomized Phase II Trial Of Gemcitabine Plus GDC-0449, A Hh Pathway Inhibitor, in Patients with Metastatic Pancreatic Cancer
Gastric/GEJ 8376 <b>ON HOLD</b> <b>AS OF 10-24-11</b>	Phase II (09-250)	A Randomized, Double Blind Placebo Controlled Phase 2 Study of FOLFOX plus or minus GDC-0449 in patients with advanced gastric and gastroesophageal junction carcinoma

**GENITOURINARY**

Renal 90802	CALGB	Randomized Phase III Trial Comparing Everolimus Plus Placebo Versus Everolimus Plus Bevacizumab for Advanced Renal Cell Carcinoma Progressing After Treatment with Tyrosine Kinase Inhibitors
Renal GU09-145	HOG	Phase I/II Study of BNC105P in Combination with Everolimus or Following Everolimus for Progressive Metastatic Clear Cell Renal Cell Carcinoma Following Prior Tyrosine Kinase Inhibitors
Prostate E3805	ECOG	CHAARTED: ChemoHormonal Therapy versus Androgen Ablation Randomized Trial for Extensive Disease in Prostate Cancer
Transitional Cell 90601	CALGB	A Randomized Double-Blinded Phase III Study Comparing Gemcitabine, Cisplatin, and Bevacizumab to Gemcitabine, Cisplatin, and Placebo in Patients with Advanced Transitional Cell Carcinoma

**GYNECOLOGIC**

**\*Due to taxol shortage no enrollment at this time\***

Cervix GOG-0240	CTSU	A Randomized Phase III Trial of Cisplatin Plus Paclitaxel with and without NCI-supplied Bevacizumab (NSC #704895, IND #7921) Versus the Non-Platinum Doublet, Topotecan Plus paclitaxel, with or without NCI-supplied Bevacizumab, In Stage IVB, Recurrent or Persistent Carcinoma of the Cervix.
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**PHASE II MULTIPLE MALIGNANCIES**

Endometrial, Ovarian, Hepatocellular, Carcinoid, Islet	Phase II 8233 (09-179)	A Phase II Trial of Temsirolimus and Bevacizumab in Patients with Endometrial, Ovarian Hepatocellular Carcinoma, Carcinoid or Islet Cell Cancers
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**Ovarian Cohort ON HOLD as of 4-11-11**

**Carcinoid OPEN (for additional 8 patients as of 9-19-11)**

**Endometrial CLOSED PERMANENTLY on 10-13-11**

**Hepatic OPEN**

**Islet OPEN**

Ovarian, Peritoneal, Fallopian tube Triple-negative breast, low-grade NHL Phase II 8788 <b>COHORT A Temp. closed 7-27-11</b>	Phase II Randomized Trial of the Combination of ABT-888 With Metronomic Oral Cyclophosphamide in Refractory BRCA Positive Ovarian, Primary Peritoneal or Ovarian High-Grade Serous Carcinoma, Fallopian Tube Cancer, Triple-Negative Breast Cancer, and Low-Grade Non-Hodgkin's Lymphoma
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**COHORT B NEARING COMPLETION OF FIRST STAGE**

**\*Due to taxol shortage no enrollment at this time\***

Epithelial, Ovarian, Peritoneal, Fallopian tube GOG-0262	CTSU	A RANDOMIZED PHASE III TRIAL OF EVERY-3-WEEKS PACLITAXEL VERSUS DOSE DENSE WEEKLY PACLITAXEL IN COMBINATION WITH CARBOPLATIN WITH OR WITHOUT CONCURRENT AND CONSOLIDATION BEVACIZUMAB (NSC #704865, IND #7921) IN THE TREATMENT OF PRIMARY STAGE II, III OR IV EPITHELIAL OVARIAN, PERITONEAL OR FALLOPIAN TUBE CANCER
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Papillary-serous ovarian Fallopian tube, peritoneal Or triple neg. breast ca. Phase II 09-293 I/II study of cediranib and olaparib in combination for treatment of recurrent papillary-serous ovarian, fallopian tube, or peritoneal cancer or for treatment of recurrent triple-negative breast cancer.  
**Pending Nov. IRB**

**HEAD AND NECK**

Head and Neck E1305 ECOG A Phase III Randomized Trial of Chemotherapy With or Without Bevacizumab in Patients with Recurrent or Metastatic Head and Neck Cancer

Head and Neck 10-428-B (8692) Phase II A T1 translational multicenter randomized phase II study of Temezirolimus versus Cetuximab plus Temezirolimus in patients with recurrent / metastatic head and neck cancer, who failed prior EGFR based therapy

**LEUKEMIA**

AML 10801 CALGB A Phase II Study of Induction (Daunorubicin/Cytarabine) and Consolidation (High-Dose Cytarabine) Chemotherapy Plus Dasatinib and Continuation Therapy with Dasatinib Alone in Newly Diagnosed Patients with Core Binding Factor Acute Myeloid Leukemia

AML E2906 CTSU Phase III Randomized Trial of Clofarabine as Induction and Post-Remission Therapy vs. Standard Daunorubicin & Cytarabine Induction and Intermediate Dose Cytarabine Post-Remission Therapy, Followed by Decitabine Maintenance vs. Observation in Newly-Diagnosed AML in older Adults  $\geq 60$  years

AML 11001 CALGB A Phase II Study Incorporating Sorafenib Into the Therapy of Patients  $\geq 60$  Years of Age With FLT3 Mutated AML

APL S0535 SWOG A Phase II Study of ATRA, Arsenic Trioxide and Gemtuzumab Ozogamicin in Patients with Previously Untreated High-Risk Acute Promyelocytic Leukemia

ALL 10403 CALGB An Intergroup Phase II Clinical Trial for Adolescents and Young Adults with Untreated ALL

ALL 10701 CALGB A Phase II Study of Dasatinib (Sprycel) as Primary Therapy Followed by Transplantation For Adult  $\geq 50$  years with Newly Diagnosed Ph+ Acute Lymphoblastic Leukemia

CLL 10404 CALGB A Randomized Phase II Study of Three Fludarabine/Antibody Combinations for Patients with Symptomatic, Previously Untreated CLL

MDS E2905 ECOG A Randomized Phase III Trial Comparing the Frequency of Major Erythroid Response (MER) to Treatment with (Revlimid®) Alone and in Combination with Epoetin Alfa (Procrit®) in Subjects with Low-or intermediate-1 Risk MDS and Symptomatic Anemia

ALL S0805 SWOG Phase II Study of Combination of Hyper-CVAD and Dasatinib (NSC-732517) with or without Allogeneic Stem Cell Transplant in Patients with Philadelphia (Ph) Chromosome Positive and/or Bcr-Abl Positive Acute Lymphoblastic Leukemia (ALL) (a BMT Study)

**LYMPHOMA**

NHL LYM08-134 HOG Phase II Study of Fludarabine, Bortezomib and Rituximab for Relapsed or Refractory Follicular Non-Hodgkin Lymphoma

NHL 8309 (09-443) Phase II A Phase I/II Investigation of Temezirolimus Plus Lenalidomide in Relapsed NHL

Hodgkins S0816 SWOG A Phase II Trial of Response Adapted Therapy of Stage III-IV Hodgkin Lymphoma Using Early Interim FDG-PET Imaging

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B-Cell Lymphoma	50303	CALGB	Phase III Randomized Study of R-CHOP v. Dose-Adjusted EPOCH-R with Molecular profiling In Untreated De Novo Diffuse Large B-Cell Lymphomas
FL	50904	CALGB	A Randomized Phase II Trial of Ofatumumab and Bendamustine vs. Ofatumumab, Bortezomib and Bendamustine in Patients with Untreated Follicular Lymphoma

**MELANOMA**

Melanoma	E1609	ECOG	A Phase III Randomized Study of Adjuvant Ipilimumab Anti-CTLA4 Therapy Versus High-Dose Interferon $\alpha$ -2b for Resected High-risk Melanoma
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**MESOTHELIOMA**

No Mesothelioma Trials Opened At This Time

**MYELOMA**

Multiple Myeloma	S0777	SWOG	A Randomized Phase III Trial of CC-5013 (Lenalidomide) and Low Dose Dexamethasone Versus Bortezomib (PS-341), Lenalidomide and Low Dose Dexamethasone for Induction In patients with Previously Untreated Multiple Myeloma Without an Intent for Immediate Autologous Stem Cell Transplant
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**RESPIRATORY**

NSCLC	E1505	ECOG	A Phase III Randomized Trial of Adjuvant Chemotherapy with or without Bevacizumab for patients with completely resected stage IB ( $\geq 4$ cm)-IIIA NSCLC
NSCLC	S0819	SWOG	A Randomized, Phase III Study Comparing Carboplatin/Paclitaxel or Carboplatin/Paclitaxel/Bevacizumab with or without Concurrent Cetuximab in patients with Advanced NSCLC
NSCLC	30607	CALGB	Randomized, Phase III, Double-Blind Placebo-Controlled Trial of Sunitinib As Maintenance Therapy in Non-Progressing Patients following an Initial Four Cycles of Platinum-Based Combination Chemotherapy in Advanced, Stage IIIB/IV NSCLC
SCLC	30504	CALGB	Combination Cisplatin, Etoposide and Sunitinib Malate for Untreated Extensive Stage Small Cell Lung Cancer
SCLC	LUN06-113	HOG	A Randomized, Double Blind, Phase II Trial of Cisplatin plus Etoposide With/without Concurrent ZD6474 in Patients with Previously Untreated Extensive Stage Small Cell Lung Cancer
SCLC	N0923	NCCTG	A Randomized Double-Blinded Phase II Study of NTX-010, a Replication-Competent Picornavirus, After Standard Platinum Containing Induction Regimens of Cytoreductive Chemotherapy for Patients with Extensive Stage Small Cell Lung Carcinoma