

CHH OPEN PROTOCOLS

**BREAST CANCER PROTOCOLS**

<b>Number</b>	<b>Name</b>	<b>Current Exp. Date</b>	<b>Remarks</b>
<b>NSABP P-2 STAR TRIAL</b>	Study of Tamoxifen and Raloxifene (STAR) for the Prevention of Breast Cancer <b>STUDY CLOSED TO ACCRUAL 5/04</b>	June 25, 2008	Breast Cancer Prevention Trial comparing Tamoxifen and Raloxifene
<b>NSABP B-35</b>	A Clinical Trial Comparing Anastrozole with Tamoxifen in Postmenopausal Patients with Ductal Carcinoma in Situ (DCIS) Undergoing Lumpectomy with Radiation Therapy	November 26, 2008	For postmenopausal women with DCIS that is ER or PR positive treated with lumpectomy and radiation therapy.
<b>CALGB 40101/ CTSU 40101</b>	Cyclophosphamide and Doxorubicin (CA) (4 vs 6 cycles) versus Paclitaxel (4 vs 6 cycles) as Adjuvant Therapy for Women with Node-Negative Breast Cancer: A 2x2 Factorial Phase III Randomized Study	October 22, 2008	A 2x2 factorial study to compare paclitaxel as a single agent adjuvant therapy, with CA as standard treatment, for women with primary breast cancer and high-risk, node-negative disease.
<b>NSABP B-38</b>	A Phase III, Adjuvant Trial Comparing Three Chemotherapy Regimens in Women with Node-Positive Breast Cancer: Docetaxel/Doxorubicin/Cyclophosphamide (TAC); Dose-Dense (DD) Doxorubicin/Cyclophosphamide Followed by DD Paclitaxel (DD AC→P): DD AC Followed by DD Paclitaxel Plus Gemcitabine (DD AC→PG) <b>STUDY CLOSED 05/03/07</b>	<b>CLOSED</b>	A Phase III adjuvant therapy trial for women with node-positive breast cancer that will compare three regimens of chemotherapy. <b>Closed study No CHH pts. on study</b>

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<b>PACCT-1</b>	Program for the Assessment of Clinical Cancer Tests (PAACT-1) : Trial Assigning Individuals	09/24/2008	A study to examine whether genes that are frequently associated with risk of recurrence for women with early stage breast cancer can be used to assign patients to the most appropriate and effective treatment. This study is for women with surgically resected ER and/or PR +, Her2/neu negative breast cancer that have not spread to the lymph nodes.
<b>NASBP B-42</b>	A Clinical Trial to Determine the Efficacy of Five Years of Letrozole Compared to Placebo in Patients Completing Five years of Hormonal Therapy Consisting of an Aromatase Inhibitor (AI) or Tamoxifen Followed by an AI in prolonging Disease-Free Survival in Postmenopausal Women with Hormone Receptor Positive Breast Cancer	October 22, 2008	For women who were diagnosed with stage I, II, or IIIA, ER-positive and/or PgR-positive breast cancer, who have completed 5 years of hormonal therapy with either 5 years Aromatase inhibitor (AI) or up to 3 years of tamoxifen followed by an AI.
<b>JMA 17</b>	Study of Letrozole vs. Placebo in Women with Primary Breast Cancer Completing Five or More Years of Adjuvant Tamoxifen.	November 26, 2008	<b>CLOSED TO ACCRUAL....TWO CHH PATIENTS ON FOLLW-UP.</b>
<b>E2197</b>	Phase III Study of Adriamycin/Taxotere vs. Adriamycin/Cytosan for the Adjuvant Treatment of Node Positive or High Risk Node Negative Breast Cancer.	July 23, 2008	<b>CLOSED TO ACCRUAL....ONE CHH PATIENT ON FOLLW-UP.</b>

## G.I. PROTOCOLS

<b>E 5202</b>	A Randomized Phase III Study Comparing 5-FU, Leucovorin and Oxaliplatin versus 5-FU, Leucovorin, Oxaliplatin and Bevacizumab in Patients with Stage II Colon Cancer at High Risk for Recurrence to Determine Prospectively the Prognostic Value of Molecular Markers	January 25,2009	A Phase III study for stage II colon cancer. To determine whether specific biological features seen in tests done on a tumor (found in the colon) can be used to predict recurrence of tumors in patients with stage II colon cancer.
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<u>Number</u>	<u>Name</u>	<u>Current Exp. Date</u>	<u>Remarks</u>
<b>CALBG 80405</b>	A phase III Trial of Irinotecan/5-FU/Leucovorin OR Oxaliplatin/5-FU/Leucovorin with Bevacizumab, OR Cetuximab (C225), OR with the combination of Bevacizumab and Cetuximab for Patients with Untreated Metastatic Adenocarcinoma of the Colon or Rectum	September 24,2008	A Phase III Study to determine if the addition of Cetuximab (C225) to chemotherapy with or without Bevacizumab prolongs survival compared to chemotherapy with Bevacizumab in patients with untreated advanced or metastatic colorectal cancer.

<b>N0147</b>	N0147, A Randomized Phase III Trial of Oxaliplatin (OXAL) Plus 5-Fluorouracil (5-FU)/Leucovorin (CF) (FOLFOX) with or without Cetuximab (C225) after Curative Resection for Patients with Stage III Colon Cancer	September 24, 2008	A Phase III Treatment Trial that is being done to determine if adding C225 to FOLFOX increases the effectiveness of FOLFOX in preventing the return of colon cancer after curative resection for patients with Stage III Colon Cancer.
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## LUNG CANCER PROTOCOLS

<b>E 1505</b>	<b>A Phase III Randomized Trial of Adjuvant Chemotherapy With or Without Bevacizumab for Patients With Completely Resected Stage IB (<math>\geq 4</math> cm) -IIIA Non-Small Cell Lung Cancer (NSCLC)</b>	September 24, 2009	The purpose of this study is to determine if adding the new drug bevacizumab to chemotherapy improves the chance for cure for patients who have had surgery for the removal of the lung cancer

## PROSTATE CANCER PROTOCOLS

<u>Number</u>	<u>Name</u>	<u>Current Exp. Date</u>	<u>Remarks</u>
<b>S0000 SELECT</b>	Selenium and Vitamin E Cancer Prevention Trial  <b>STUDY CLOSED TO ACCRUAL 6/04</b>	November 26, 2008	<u>Prostate Cancer Prevention Trial</u> to assess the effect of selenium and vitamin E alone and in combination on the clinical incidence of prostate cancer.

## GYN PROTOCOLS

<u>Number</u>	<u>Name</u>	<u>Current Exp. Date</u>	<u>Remarks</u>
<b>GOG 0182</b>	A Phase III Randomized Trial of Paclitaxel and Carboplatin <i>versus</i> Triplet or Sequential Doublet Combinations in Patients with Epithelial Ovarian or Primary Peritoneal Carcinoma <b>STUDY CLOSED TO ACCRUAL 9/1/04</b>	March 26, 2008	For patients with stage III or IV ovarian epithelial or serious primary peritoneal carcinoma.
<b>GOG 0198</b>	A Randomized Study of Tamoxifen versus Thalidomide (NSC #66847) in Patients with Biochemical Recurrence Only Epithelial Ovarian Cancer, Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma After First Line Chemotherapy.	<b>CLOSED 11/2007</b>	For patients with a biochemical recurrence of ovarian epithelial, fallopian tube, or primary peritoneal cancer after first-line chemotherapy. <b>Closed Study - No CHH pts. enrolled in study</b>

## MULTIPLE MYELOMA

<b>E4A03</b>	A Randomized Phase III Study of CC-5013 plus Dexamethasone versus CC-5013 plus Low Dose Dexamethasone in Multiple Myeloma with Thalidomide plus Dexamethasone Salvage Therapy for Non-Responders	March 27, 2008	For patients that are newly diagnosed (within the past 90 days) with symptomatic multiple myeloma. This study will evaluate the response rate and toxicity of CC-5013 plus dexamethasone (standard dose) versus CC-5013 plus low dose dexamethasone after 4 cycles of treatment, and will also evaluate if CC-5013 plus low dose dexamethasone will have similar response rate with lower toxicity.
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