

**St. Vincent's Medical Center
Oncology Clinical Trials
Open Studies Update (2/06/09)**

Study Title	Principal Investigator	Description
Breast Cancer		
SVMC 104: A Phase V Single Site Prospective, Non-randomized Study of the MammoSite Radiation Therapy Delivery System (Breast Brachytherapy Applicator) To Evaluate Local Tumor Control, Cosmetic Outcome and Toxicities	Dr. Deborah Fang 203-576-5085	Eligibility 45 y.o. Negative margins T1N0, DCIS, TisN0M0
PACCT-1: TAILORx Trial/SVMC 160 ECOG/BCI: Program for the Assessment of Clinical Cancer Test: Trial Assigning Individualized Options for Treatment	Dr. Anthy Demestihias 203-332-4744	Eligibility Invasive breast cancer ER/PR positive HER2 negative Negative axillary nodes Tumor size 1-5 cm Standard chemo/hormonal therapy
SVMC: Moving for Health: A Feasibility Study	Cindy Czaplinski RN, MS 203-576-6234 Awaiting administrative approval submitted 7/7/08 for submission 11/01/08	Purpose To evaluate nurse-delivered exercise intervention on the muscle strength of oncology patients APPROVED 12/08/08
SVMC: Building a Foundation for Health for Women of Color: Breast Cancer Survivors	Cindy Czaplinski RN, MS 203-576-6234 Awaiting administrative approval submitted 8/27/08 For IRB submission 10/1/08-IFC changes required submitted 10/27/09	Purpose Educate women who participate about breast cancer, provide support and help APPROVED 11/18/08
Gastrointestinal Cancer		
ACOSOG Z6041/SVMC 139 A Phase II Study of Neoadjuvant Chemoradiotherapy Comprising Capecitabine, Oxaliplatin, and Radiotherapy Followed By Local Excision in Patients With Stage I Adenocarcinoma of the Rectum	Dr. Stuart Marcus 203-576-6101	Eligibility Histologically confirmed invasive rectal Adenocarcinoma Radiation therapy M-F for 5 weeks Capecitabine po bid with 2-hour infusion oxaliplatin once a week in weeks 1, 2, 4, and 5 4-8 weeks later, surgery to remove the tumor

<p>CALGB80101/SVMC144 Phase III Intergroup Trial of Adjuvant Chemoradiation After Resection of Gastric or Gastroesophageal Adenocarcinoma</p>	<p>Dr. Stuart Marcus 203-576-6101</p>	<p><u>Eligibility</u> No metastatic cancer, No previous chemotherapy or radiation therapy, No more than 8 weeks since surgery. <u>Group one:</u> will receive infusions of leucovorin and fluorouracil as well as radiation. <u>Group two:</u> will receive infusions of epirubicin, cisplatin, and fluorouracil as well as radiation.</p>
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Genitourinary Cancer

<p>RTOG 0521:SVMC 141 A Phase III Protocol of Androgen Suppression (AS) and Radiation Therapy (RT) vs AS and RT Followed by Chemotherapy with Docetaxel and Prednisone for Localized, High-Risk,</p>	<p>Dr. Christopher Iannuzzi 203-576-5085</p>	<p><u>Eligibility</u> PSA ≤ 150 ng/mL, no distant metastases, No previous radical prostatectomy, cryosurgery, or Bilateral orchiectomy, No previous chemotherapy for prostate cancer. <u>Group one:</u> androgen suppression therapy for 2 years. Beginning 8 weeks after the start, undergo radiation therapy 5 days a week for approximately 8 wk <u>Group two:</u> same initial hormone and radiation treatment as group one. But beginning 4 weeks after the initial treatment, patients will also receive a 1-hour infusion of docetaxel once in week 1 and prednisone by mouth once a day. Treatment with docetaxel and prednisone may repeat every 3 weeks for up to six courses.</p>
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<p>ECOG: ASSURE: SVMC 169 Adjuvant Sorafenib or Sunitinib for Unfavorable Renal Carcinoma</p>	<p>Dr. Berard 203-334-7400</p>	<p>Eligibility Full Surgical Resection Renal Cell Carcinoma T1B, T2,T3,T4 N any CT show no residual disease No prior treatment No collecting duct or medullary carcinoma Must be 3-10 weeks post surgery at randomization</p>
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Lung Cancer

<p>CALGB 140503/SVMC 166 A Phase III Randomized Trial of Lobectomy versus Sublobar Resection for Small (< 2 CM) Peripheral Non-Small Cell Cancer Cancer</p>	<p>Dr. DiMeo 203-576-8507</p>	<p>Eligibility ≤2 peripheral lung nodule seen by CT scan Tumor must be removed by either wedge/segment No prior malignancy, >5 year life expectancy, no prior chemo/radiation therapy. Confirmed NSCLC, N0 on levels 4,7,10 on right And 5, 6,7,10 on left.</p>
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PREVENTION TRIALS

<p>SVMC:110 Case Control Study of Pancreas Cancer Etiologic Factors</p>	<p>Yale University</p>	<p>Purpose To discover how dietary, occupational and certain medical factors may cause pancreatic disease.</p>
<p>SVMC:111 Epidemiologic Study of the Uterus Cancer</p>	<p>Yale University</p>	<p>Purpose To discover how dietary, physical activity and certain medical factors may cause uterus diseases.</p>
<p>SVMC:162 Meningioma: Risk Factors and Quality of Life</p>	<p>Yale University</p>	<p>Purpose To study the changes or alterations in these genes to determine how frequently they occur and whether there is any relationship between any changes and brain lesions</p>
<p>SVMC:161 Environment, Gene, and Testicular Cancer Risk</p>	<p>Yale University</p>	<p>Purpose Collection of a urine specimen To measure endogenous and related hormones</p>

On the Cutting Edge

<p>GENETECH A Phase II Study of Bevacizumab in Combination with Carboplatin and Paclitaxel in</p>	<p>Dr. Dressler IRB administrative application submitted 9/3/08</p>	<p>Eligibility No prior chemo, primary peritoneal carcinoma, fallopian tube, epithelial ovarian carcinoma, Stage III suboptimal residual</p>
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Patients with Ovarian, Fallopian Tube, or Peritoneal Carcinoma	Budget to be submitted 10/6/08 ON HOLD	disease following initial surgery or biopsy, or stage IV disease. Histologic cell types: serous, endometrioid, mucinous, undifferentiated, clear cell, mixed epithelial, transitional cell, malignant Brenner's tumor, NOS tumor.
ACOSOG Z5041: A Phase II Study for Preoperative Gemcitabine and Erlotinib Plus Pancreatectomy and Postoperative Gemcitabine and Erlotinib for Patients with Operable Pancreatic Adenocarcinoma	Dr. Stuart Marcus 203-576-6101 ADMINISTRATIVE APPLICATION IN PROCESS	Eligibility Adenocarcinoma of the pancreatic head Resectable tumor CA 19-9 <1,000 No prior treatment with EGFR for dz. Active infection tx. With IV Abx. at registration
ECOG 1505: SVMC A Phase III Randomized Trial Of Adjuvant Chemotherapy With or Without Bevacizumab for Patients With Completely Resected Stage 1B (≥ 4 cm) – IIIA Non-Small Cell Lung Cancer (NSCLC)	Dr. Paul Berard 203-334-7400 Administrative approval submitted 9/4/08 Budget to be submitted 10/6/08 IFC reviewed 1/21/09 PRELIMINARY APPROVAL 2/3/09 For IEB submission	Eligibility Complete resection of tumor No history of cancer no hemoptysis Normal laboratory data No active infection No wound/abcess Therapeutic anticoagulation without thrombotic disease
NCCTG NO636: ALTTO A Randomized, Multi-Centre, Open-Label, Phase III Study of Adjuvant Lapatinib, Trastuzumab, their Sequence and Their combination in women with HER2 (ErbB2) Positive Primary Breast Cancer (BIG 2-06/NO6D/EGF106708)	Dr. Sandhya Dhanjal ADMINISTRATIVE APPLICATION	
CALGB 40503:SVMC 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 CA	Dr. Anthy Demestihias 203-332-4744 ADMINISTRATIVE APPLICATION	Eligibility Inoperable locally advanced or MBC ER and/or PR positive Postmenopausal Measurable or non-measurable disease per RECIST No CNS involvement, HTN, wound issues, DVT, PE, MI, TIA/CVA
SVMC: Beneficial Affects of the Patient Nurse Navigator that is Dependent on Characteristic of Education, Ethnicity, Race, Diversity, Insurance Status, Language and Age	Dr. Stuart Marcus 203-576-6101 ADMINISTRATIVE APPLICATION AND BUDGET SENT 11/17/08 Budget approved 1/3/09 IRB submission 2/1/09	Purpose To evaluate the importance of the nurse navigator
SVMC: Onyx NU07B1-A Double Blind, Randomized Phase 2b Study Evaluating the Efficacy and Safety of Sorafenib Compared to Placebo when administered in combination with Paclitaxel in Patients with Locally Recurrent	Dr. Kenneth Dressler 203-255-4545 Applied for Administrative Application on 6/23/08 Submitted to IRB 10/1/08 for 10/20/08 meeting-IFC changes	Purpose To compare progression free survival (PFS) in patients with sorafenib and Paclitaxel versus patients treated with placebo and Paclitaxel as a first-line therapy for locally recurrent or metastatic breast cancer CLOSED TO ACCURAL

or MBC	required submitted 10/30/08	

Please contact Teresa White, Clinical Research Coordinator, at 203-576-6329 for more information