

# *Division of Internal Medicine Quarterly Report June 2008*

<i>PIName</i>	<i>LCID</i>	<i>StudyName</i>	<i>StudyStatus</i>	<i>Open to Accrual</i>
<b>Cardiovascular Medicine</b>		<i>Count of Department Studies: 33</i>		
<i>Sidney Alexander, M.D.</i>				
2003-029		A Randomized Double-Blind Placebo-Controlled MultiCenter PH III Study Of Rosuvastatin(CRESTOR®) 20 mg In The Primary Prevention Of Cardiovascular Events Among Subjects With Low Levels Of LDL-Cholesterol And Elevated Levels Of C-Reactive Protein (JUPITER)	Open	No
<i>David E. Gossman, M.D.</i>				
2006-046		The MASS COMM TRIAL-A Randomized Trial To Compare Percutaneous Coronary Intervention Between Massachusetts Hospitals With Cardiac Surgery-On-Site And Community Hospitals Without Cardiac Surgery-On-Site	Open	Yes
<i>Bruce Hook, M.D.</i>				
2007-007		Focus AF: Focused Circumferential Ultrasound For The Treatment Of Atrial Fibrillation	Open	Yes
<i>Sherif B. Labib, M.D.</i>				
2006-001		MultiCntr Dbl-Blnd Rndmzd Stdy To Establish The Clinical Benefit & Safety Of Vytorin(Ezetimibe/Simvastatin Tablet) vs. Simvastatin Monotherapy In High-Risk Pts Presenting W/ Acute Coronary Syndrome(IMProved Reduction Of Outcomes:Vytorin Efficacy Intr'l T	Open	Yes
<i>David T. Martin, M.D.</i>				
2004-102		MultiCenter Automatic Defibrillator Implantation Trial With Cardiac Resynchronization Therapy (MADIT-CRT)	Open	Yes
2006-070		Clinical Research Evaluation Of The ASSURE™ Device Atrial And Ventricular Tachyarrhythmia Therapies Registry (Reassure AV Registry)	Open	No
2001-064		A Case Control Study Of T-Wave Alternans (TWA) In Diabetic Patients With And Without Coronary Artery Disease	Open	Yes

<u><i>PIName</i></u>	<u><i>LCID</i></u>	<u><i>StudyName</i></u>	<u><i>StudyStatus</i></u>	<u><i>Open to Accrual</i></u>
2000-076		A Pilot Study Of T Wave Alternans In Sleep Apnea Syndrome	Open	No
2008-023		The IMPACT Study: The IMPACT Of BIOTRONIK Home Monitoring Guided Anticoagulation On Stroke Risk In Patients With Implanted ICD And CRT-D Devices	Open	Yes
2007-078		REPLACE Registry	Open	Yes
2007-027		Tailored Treatment Of Permanent Atrial Fibrillation-TTOP AF Trial	Open	Yes
<b><i>Richard W. Nesto, M.D.</i></b>				
2000-085		The Role Of Inflammation As Mediated By C-Reactive Protein, Interleukin-6 And Complement Activation In Acute Coronary Events	Open	Inactive
2003-006		A Randomized Double-Blind Trial To Assess Taxus™ Paclitaxel-Eluting Coronary Stents, Slow-Release Formulation In The Treatment Of De Novo Coronary Lesions	Open	No
2003-042		A Prospective Randomized Trial Evaluating The Slow-Release Formulation Taxus™ Paclitaxel-Eluting Coronary Stent In The Treatment Of In-Stent Restenosis	Open	No
<b><i>Florence Parrella, M.D.</i></b>				
2004-058		Evaluation Of The Safety And Efficacy Of The Optimizer™ System With Active Fixation Leads In Subjects With Heart Failure Resulting From Systolic Dysfunction: FIX-HF-5	Open	No
2006-052		NAVISTAR® /THERMOCOOL® Catheter For The Radiofrequency Ablation Of Symptomatic Paroxysmal Atrial Fibrillation IDE# G030236	Open	No

<u>PIName</u>	<u>LCID</u>	<u>StudyName</u>	<u>StudyStatus</u>	<u>Open to Accrual</u>
2004-080		MVP Trial: MVP vs. VVI40 Pacing Trial	Open	No
<b><i>Thomas C. Piemonte, M.D.</i></b>				
2007-098		The US Study For Evaluating Endovascular Treatments Of Lesions In The Superficial Femoral Artery And Proximal Popliteal By Using The Protégé Everflex Nitinol Stent System II- DURABILITY II	Open	Yes
2002-012		JOMED JOSTENT Coronary Stent Graft For Use Under FDA Humanitarian Device Exemption	Open	Yes
2001-096		JOMED JoStent Coronary Stent Graft For Use Under FDA Humanitarian Device Exemption	Open	Inactive
2007-095		SONOMA: The Nexstent® Carotid Stent System: A Post Market Approval Evaluation Study In Conjunction With The Filterwire EZ™ Embolic Protection System	Open	Yes
2008-024		PROTECT II: A Prospective Multi-Center Randomized Controlled Trial Of The IMPELLA® RECOVER® LP 2.5 System Versus Intra Aortic Balloon Pump (IABP) In Patients Undergoing Non Emergent High Risk PCI	Open	Pending
<b><i>Nicholas P. Tsapatsaris, M.D.</i></b>				
2007-038		Prosp Rndmzld Dbl-Bld Dbl-Dummy Parallel-Grp Mlticntr Event-Driven Non-Inferiority Study Cmpng Efficacy & Sfty Once-Daily Oral Rivaroxaban(BAY59-79-39) w/Adjusted-Dose Oral Warfarin Prev of Stroke & Non-Cntrl Nervous System Systemic Embolism (ROCKET AF)	Open	Yes
2006-042		Physician Alerts To Prevent DVT And Pulmonary Embolism In Hospitalized Patients(ALERT)	Open	No
2005-015		Cardiovascular Outcomes in Renal Atherosclerotic Lesions Rndmizld & MultiCtr Two-Grp Clinical Trial To Assess Best Trtmnt For Pts w/ High Blood Pressure & Renal Artery Stenosis: Stenting w/ Anti-Hypertensive Medical Therapy Cmprd To Medical Therapy Alone	Open	Yes

***David M. Venesy, M.D.***

<u><i>PIName</i></u>	<u><i>LCID</i></u>	<u><i>StudyName</i></u>	<u><i>StudyStatus</i></u>	<u><i>Open to Accrual</i></u>
2007-049	REDUCEHF:	REduce Decompensation events Utilizing intraCardiac prEssures in patients with chronic HF	Open	Yes
2004-065	REVERSE:	Resynchronization Reverses Remodeling In Systolic Left Ventricular Dysfunction	Open	No
<b><i>Sergio Waxman, M.D.</i></b>				
2007-104	Protocol LANTU_L_01687 INTENSIVE:	Multicenter Ph 3b Stratified Randomized Open Label Clinical Trial To Evaluate Efficacy Of Intensive Apidra®/Lantus® Therapy Vs Sliding Scale Insulin On Infarct Size In Hyperglycemic Sbjcts w/ Anterior STEMI Undergoing PCI	Open	Yes
2007-112	Randomized Dbl-Blind Parallel Grp Ph 3	Efficacy and Safety Study of AZD6140 Compared w/ Clopidogrel For Prevention Of Vascular Events In Patients w/ Non-ST Or ST Elevation Acute Coronary Syndromes(ACS)[PLATO-A Study Of Platelet Inhibition And Pt Outcomes]	Open	Pending
2006-050	Coronary Artery Plaque Characterization By NIR Spectroscopy In Patients Undergoing Elective Percutaneous Coronary Intervention (Feasibility Pivotal Study)		Open	No
2005-046	Natural History of Vulnerable Coronary Plaques		Open	Yes
2008-026	A Clinical Evaluation Of The Medtronic Endeavor Zotarlimus-Eluting Coronary Stent System In The Treatment Of Single DE NOVO Lesions. THE ENDEAVOR: SMALL VESSEL STENTING (SVS) REGISTRY		Open	Pending
2006-063	IMMEDIATE TRIAL: Immediate Myocardial Metabolic Enhancement During Initial Assessment And Treatment In Emergency Care		Open	Yes

**Endocrinology**

*Count of Department Studies: 4*

***Gary W. Cushing, M.D.***

2000-071	BYPASS Angioplasty Revascularization Investigation 2 Diabetes (BARI2D)		Open	No
----------	--	--	------	----

<u>PIName</u>	<u>LCID</u>	<u>StudyName</u>	<u>StudyStatus</u>	<u>Open to Accrual</u>
---------------	-------------	------------------	--------------------	------------------------

**Nicholas A. Tritos, M.D., DSc**

2006-073		PFIZER International Metabolic Study (KIMS)	Open	Yes
2006-032		Characterization Of Mechanisms Involved In The Pathogenesis Of Hypoglycemia After Gastric Bypass Surgery For Obesity	Open	Yes
2007-076		Investigation Of Endocrine Mechanisms Mediating Weight Loss After GI Sleeve Implantation In Morbidly Obese Subjects	Open	Yes

**Gastroenterology**

*Count of Department Studies: 4*

**Amy E. Barto, M.D.**

2006-092		M06-808 A Multi-Center Open Label Treatment Protocol Of The Human Anti-TNF Monoclonal Antibody Adalimumab In Patients With Moderate To Severe Crohn's Disease With Previous Exposure To Infliximab	Open	No
----------	--	--	------	----

**Marvin Berman, M.D.**

2001-007		A Prospective, Randomized, MultiCenter, Open-Label, Comparative Safety Study Of PEGASYS VS PEGASYS Plus RIBAVIRIN Treatment vs A Twelve Week Treatment Delay In Patients With Chronic Hepatitis C	Open	Inactive
----------	--	---	------	----------

**Andrew S. Warner, M.D.**

2002-023		The Crohn's Therapy, Resource, Evaluation And Assessment Tool Registry (TREAT REGISTRY)	Open	No
95-043		Clinical Trial Of Aspirin And Folic Acid In The Prevention Of Large Bowel Adenomas	Open	No

**Geriatrics**

*Count of Department Studies: 1*

**Wayne Saltsman, M.D., Ph.D.**

<u>PIName</u>	<u>LCID</u>	<u>StudyName</u>	<u>StudyStatus</u>	<u>Open to Accrual</u>
2006-028		Hypertension Education For Lahey Patients (H.E.L.P.)	Open	Yes

## Hematology

*Count of Department Studies: 8*

### *Simon Mantha, M.D.*

2007-059		PHIII Rndmzsd Dbl-Bld Parlel-Grp Stdy Efficacy & Safety Oral Dabigatran EteXilate(150mg bid)Cmprd Warfarin(INR 2.0-3.0)6 Mth Trtmnt Acute Symptomatic Venous Thromboembolism Flwg Initial Trtmnt(5-10days)w/ Parenteral Anticoagulant Apvrld Indication RE-COVER	Open	Yes
2007-060		Ph III Randomized Multicenter Double-Blind Parallel-Group Active Controlled Study To Evaluate The Efficacy & Safety Of Oral Dabigatran EteXilate (150mg bid) Compared To Warfarin (INR 2.0-3.0) For The Secondary Prevention Of Venous Thromboembolism RE-MEDY	Open	Yes

### *Arthur P. Rabinowitz, M.D.*

2007-002		AMG 531: A Randomized Double Blind Placebo Controlled Study Evaluating The Efficacy And Safety Of AMG 531 Treatment Of Subjects With Low Or Intermediate Risk Myelodysplastic Syndrome (MDS) Receiving Hypomethylating Agents	Open	Yes
2000-033		CALGB 59903: Random PH III Trial Comp Early HI Dose Chemo & Autologous Stem Cell Transplant To Conventional Dose CHOP Chemo+Rituximab For CD20+Bcell Lymphomas(w/ Posbl Late A.S.C. Transplant) Pts w/Diffuse Aggrsve NonHodgkins Lymph In High-Inter & High	Open	No
2007-040		NEMC QPP-QPP, A Protease That Prevents Apoptosis In Quiescent Cells	Open	No

### *David Steinberg, M.D.*

98-086		Expanded Access Study Of Iodine-131 ANTI-B1 Antibody For Relapsed/Refractory Low-Grade And Transformed Low-Grade Non-Hodgkin's Lymphoma	Open	No
2004-052		CALGB 50102: S0016: A PH III TRIAL OF CHOP + RITUXIMAB VS. CHOP + IODINE 131-LABELED MONOCLONAL ANTI-B1 ANTIBODY(TOSITUMOMAB) FOR TREATMENT OF NEWLY DIAGNOSED FOLLICULAR NON-HODGKIN'S LYMPHOMAS	Open	Yes

### *Neil Weiner, M.D.*

<u>PIName</u>	<u>LCID</u>	<u>StudyName</u>	<u>StudyStatus</u>	<u>Open to Accrual</u>
2008-035	ECOG E2902: A Phase III Randomized Study Of Farnesyl Transferase Inhibitor R115777 In Acute Myeloid Leukemia (AML) Patients In Second Or Subsequent Remission Or In Remission After Primary Induction Failure Or Patients Over Age 60 In First Remission		Open	Yes

## Infectious Diseases

*Count of Department Studies:* **8**

### *Donald E. Craven, M.D.*

2006-093	Early Access Of MK-0518 In Combination With An Optimized Background Antiretroviral Therapy (OBT) In Highly Treatment Experienced HIV-1 Infected Patients With Limited To No Treatment Options		Open	No
----------	---	--	------	----

### *Pierre Forgacs, M.D.*

95-046	A Study Of BCG Excretion After Intravesical BCG Treatment		Open	No
--------	---	--	------	----

### *Winnie Ooi, M.D., DMD, MPH*

2007-100	IND Protocol: Intravenous Artesunate For Treatment Of Severe Malaria In The United States		Open	Yes
2008-022	Seroprevalence Of Dengue And Other Related Viruses* In Travelers Seen In The Boston Area Travel Medicine Network (BATMN) *Chikungunya, Yellow Fever, Japanese Encephalitis And West Nile Virus		Open	Yes
2008-012	Protocol For Demographic Analysis Of Travelers Seen In The Boston Area Travel Medicine Network (BATMN): Focus On High-Risk Travelers		Open	Pending
2007-021	Treatment Of Leishmaniasis With IV Pentostam (Sodium Stibogluconate)		Open	Yes
2008-015	Hepatitis B Screening In Foreign-Born Travelers		Open	Yes

<u>PIName</u>	<u>LCID</u>	<u>StudyName</u>	<u>StudyStatus</u>	<u>Open to Accrual</u>
2004-105		Diethylcarbamzine Citrate (DEC) For Treatment Of Filariasis	Open	Yes

## Nephrology

*Count of Department Studies: 1*

### *Beth A. Bouthot, M.D.*

2007-051		Mycophenolic acid Observational Renal Transplant Program: PHIV Non-Intervent Mlticntr Open Label Prospect Observ Study Of Safety Effectiv Tolerabty & Compliance Immunosuppressive Regimens Using Mycophenolic Acid To Treat De Novo Renal Trans Pts Routine	Open	Yes
----------	--	--	------	-----

## Oncology

*Count of Department Studies: 58*

### *Neela Natarajan, M.D.*

2007-042		GOG 0218:PIII Trial Carboplatin & Taxol+Placebo vs Carboplatin & Taxol+Concurrent Bevacizumab Follwd By Placebo vs Carboplatin & Taxol+Concurrent & Extnded Bevacizumab Women w/ Newly Diag Prev Untreat Stage III/IV Epithelial Ovarian & Prim Peritoneal CA	Open	Yes
2006-080		A Phase 3 Study of SU011248 In Combination With Paclitaxel Versus Bevacizumab With Paclitaxel In The First-Line Advanced Disease Setting In Patients Having Breast Cancer	Open	Yes
2008-006		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	Open	Yes
2008-019		Program For The Assessment Of Clinical Cancer Tests (PACCT-1): Trial Assigning Individualized Options For Treatment: The TAILORx Trial	Open	Yes
2005-057		A National Web-Based Randomized Phase III Study Of Erlotinib Or Placebo Following Concurrent Docetaxel, Carboplatin And Thoracic Radiotherapy In Patients With Inoperable Stage III Non-Small Cell Lung Cancer	Open	Yes
2007-074		Protocol AVF4095g: A Phase III Multicenter, Randomized, Blinded, Placebo-Controlled Trial Of Carboplatin And Gemcitabine Plus Bevacizumab In Patients With Platinum-Sensitive Recurrent Ovary, Primary Peritoneal Or Fallopian Tube Carcinoma	Open	Yes

### *Francis W. Nugent, M.D.*

<u>PIName</u>	<u>LCID</u>	<u>StudyName</u>	<u>StudyStatus</u>	<u>Open to Accrual</u>
2007-001		A Phase II Open-Label Study Of The Safety And Efficacy Of Atiprimod Treatment For Patients With Low To Intermediate Grade Neuroendocrine Carcinoma	Open	No
<b><i>Paola Rode, M.D.</i></b>				
99-080		CALGB 9581:Phase III Randomized Study Of Adjuvant Immunotherapy With Monoclonal Antibody 17-1A Versus No Adjuvant Therapy Following Resection For Stage II (Modified Astlercoller B2) Adenocarcinoma Of The Colon	Open	No
2006-082		ECOG 2805: ASSURE: Adjuvant Sorafenib Or Sunitinib For Unfavorable Renal Carcinoma	Open	Yes
2004-001		CALGB 90206: A Randomized Phase III Trial of Interferon Alfa-2B or Interferon Alfa-2B Plus Bevacizumab In Patients With Advanced Renal Carcinoma	Open	No
2007-003		Rndmzd Open Label MultiCenter Study Of XRP6258 At 25mg/m <sup>2</sup> In Comb. w/ Prednisone Every 3 Wks Comprd To Mitoxantrone In Open Comb. w/ Prednisone For The Treatment Of Hormone Refractory Metastatic Prostate CA Previously Treated w/ A Taxotere® Containing Regimen	Open	Yes
2007-035		A Randomized Open Label Multicenter Phase III 2-Arm Study Of Androgen Deprivation With Leuprolide +/- Docetaxel For Clinically Asymptomatic Prostate Cancer Subjects With A Rising PSA Following Definitive Local Therapy	Open	Yes
2005-037		CALGB 90401: A Randomized Double-Blinded Placebo Controlled Phase III Trial Comparing Docetaxel And Prednisone With And Without Bevacizumab(IND#7921, NSC #704865) In Men With Hormone Refractory Prostate Cancer	Open	No
98-005		CALGB 9594: Intermittent Androgen Deprivation In Patients With Stage D2 Prostate Cancer: PHASE III	Open	Yes
<b><i>Todd D. Shuster, M.D.</i></b>				
95-066		CALGB 9592: Phase III Comparison Between Concurrent Chemotherapy Plus Radiotherapy And Concurrent Chemotherapy Plus Radiotherapy Followed By Surgical Resection For Stage IIIA (N2) Non-Small Cell Lung Cancer	Open	No

<i><u>PIName</u></i>	<i><u>LCID</u></i>	<i><u>StudyName</u></i>	<i><u>StudyStatus</u></i>	<i><u>Open to Accrual</u></i>
94-025	CALGB 9343:	Evaluation Of Lumpectomy, Tamoxifen, And Irradiation Of The Breast Compared With Lumpectomy Plus Tamoxifen In Women 70 Years Of Age Or Older Who Have Carcinoma Of The Breast That Is Less Than Or Equal To 2 cm & Clinically Neg	Open	No
94-031	CALGB 9344:	Doxorubicin Dose Escalation With Or Without Taxol For Node Positive Breast Cancer: Phase III INTERGROUP Study	Open	No
99-051	CALGB 89803:	Phase III Intergroup Trial IRINOTECAN 9CPT-11) (NSC#616348) Plus Fluorouracil/Leucovorin (5FU/LV) Versus Fluorouracil/Leucovorin Alone After Curative Resection For Patients With Stage III Colon Cancer	Open	No
99-007		Docetaxel, Estramustine And Short Term Androgen Withdrawal For Patients With A Rising PSA After Definitive Local Treatment	Open	No
2001-049	NSABP Protocol C-07:	A Clinical Trial Comparing 5-Fluorouracil (5-FU) Plus Leucovorin (LV) And Oxaliplatin With 5-FU Plus LV For The Treatment Of Patients With Stages II And III Carcinoma Of The Colon	Open	No
2006-012		Randomized Dbl-Blnd Placebo-Controlled PHIIIB Trial Comparing Bevacizumab Therapy W/ or Without Erlotinib After Completion Of Chemotherapy With Bevacizumab For The First-Line Treatment Of Locally Advanced, Recurrent Or Metastatic Non-Small Cell Lung CA	Open	Yes
99-034	NSABP B-30:	A Three-Arm Randomized Trial To Compare Adjuvant Adriamycin & Cyclophosphamide Followed By Taxotere(AC->t); Adriamycin & Taxotere(AT); & Adriamycin, Taxotere, & Cyclophosphamide(ATC) In Breast Cancer Patients With Positive Axillary Nodes	Open	No
2000-086	NSABP B-34:	A Clinical Trial Comparing Adjuvant Clodronate Therapy vs Placebo In Early-Stage Breast Cancer Patients Receiving Systemic Chemotherapy and/or Tamoxifen or No Therapy (PHASE III Study)	Open	No
2002-040	CALGB 40101:	Cyclophosphamide And Doxorubicin(CA X4 Cycles) Versus Paclitaxel (4 Cycles) As Adjuvant Therapy For Breast Cancer In Women With 0-3 Positive Axillary Lymph Nodes: A Phase III Randomized Study	Open	Yes
97-031		A Randomized, Double-Blind Trial Comparing Arimidex Alone With Nolvadex Alone With Arimidex And Nolvadex In Combination As Adjuvant Treatment In Post-Menopausal Women With Breast Cancer (Trial No. 10331L/0029)	Open	No

<i><u>PIName</u></i>	<i><u>LCID</u></i>	<i><u>StudyName</u></i>	<i><u>StudyStatus</u></i>	<i><u>Open to Accrual</u></i>
99-033	CALGB 49802:	Phase III Study Of Adriamycin/Taxotere Versus Adriamycin/Cytoxan For The Adjuvant Treatment Of Node Positive Or High Risk Node Negative Breast Cancer	Open	No
98-045	CALGB C9741:	A Randomized Phase III Trial Of Sequential ChemoTX Using Doxorubicin, Paclitaxel&Cyclophosphamide Or Concurrent Doxorubicin&Cyclophosphamide Followed By Paclitaxel At 14 Or 21 Day Intervals In Women With Node Positive Stage II/IIIA Breast CA	Open	No
2001-002	Selenium And Vitamin E Cancer Prevention Trial (SELECT)		Open	No
98-046	CALGB 9633:	A Phase III Study Of Adjuvant Chemotherapy After Resection For Patients With T2N0 Stage I NonSmall Cell Carcinoma Of The Lung	Open	No
99-041	CALGB 49805:	A Phase III Randomized Double Blind Study of Letrozole Versus Placebo In Women With Primary Breast Cancer Completing Five Or More Years Of Adjuvant Tamoxifen	Open	No
2004-092	A Phase II Dose-Response Pilot Study Of $\pm$ 3,4-Methylenedioxyamphetamine(MDMA)-Assisted Psychotherapy In Subjects With Anxiety Associated With Advanced-Stage Cancer		Open	Yes
99-041ADD	Double Blind Randomization to Letrozole Or Placebo For Women Prev Diagnosed w/ Primary Breast Cancer Completing 5 Yrs Of Adjuvant Aromatase Inhibitor Either As Initial Therapy Or After Tamoxifen(Including Those In The MA.17 Study) Add To:CALGB 49805 Study		Open	Yes
2007-079	ECOG E1505:	A Phase III Randomized Trial Of Adjuvant Chemotherapy With Or Without Bevacizumab For Patients With Completely Resected Stage IB(= 4cm)-IIIA Non-Small Cell Lung Cancer (NSCLC)	Open	Yes
2005-011	A Randomized, Open-Label, Controlled, Clinical Trial of Chemotherapy and Bevacizumab With and Without Panitumumab in The First-Line Treatment of Subjects With Metastatic Colorectal Cancer		Open	No
90-037	CALGB 8897:	Phase III Comparison Of Adjuvant Chemotherapy With Or Without EndocrineTherapy In High-Risk, Node Negative Breast Cancer Patients	Open	No

<u><i>PIName</i></u>	<u><i>LCID</i></u>	<u><i>StudyName</i></u>	<u><i>StudyStatus</i></u>	<u><i>Open to Accrual</i></u>
2006-081		CALGB/SWOG C80405 PhIII Trial Of Irinotecan/5-FU/Leucovorin Or Oxaliplatin/5-FU/Leucovorin With Bevacizumab Or Cetuximab(C225) Or With The Combination Of Bevacizumab & Cetuximab For Patients With Untreated Metastatic Adenocarcinoma Of The Colon Or Rectum	Open	Yes
2007-012		AVF3995g: A Placebo-Controlled, Double-Blind, Multicenter, Randomized, Phase II Study Of Bevacizumab In Previously Untreated Extensive-Stage Small Cell Lung Cancer	Open	Yes
2004-097		NSABP B38: PhIII Adjuvant Trial Cmpng 3 Chemotherapy Regimens In Women w/ Node-Positive Breast Cancer: DocEtaxel/Doxorubicin/Cyclophosphamide(TAC) (DD) Doxorubicin/Cyclophosphamide Fld By DD Paclitaxel (DD AC P) DDAC Fld By DD Paclitaxel + Gemcitabin	Open	No
2003-065		A PhIII Trial Evaluating The Role Of Ovarian Function Suppression & The Role Of Exemestane As Adjuvant Therapies For Premenopausal Women With Endocrine Responsive Breast Cancer	Open	Yes
<b><i>Keith E. Stuart, M.D.</i></b>				
2007-034		ECOG E5204: Intergroup Randomized Phase III Study Of Post-Operative Oxaliplatin 5-Fluorouracil And Leucovorin vs Oxaliplatin 5-Fluorouracil Leucovorin And Bevacizumab For Patients With Stage II or III Rectal Cancer Receiving Pre-Operative Chemoradiation	Open	Yes
2007-097		S0600: Ph III Trial Of Irinotecan-Based Chemotherapy Plus Cetuximab(NSC-714692) w/ Or w/o Bevacizumab(NSC-704865) As Second-Line Therapy For Patients w/ Metastatic Colorectal Cancer Who Have Progressed On Bevacizumab With Either Folfox, Optimox Or Xelox	Open	Yes
2008-009		CALGB 80101: Phase III Intergroup Trial Of Adjuvant Chemoradiation After Resection Of Gastric Or Gastroesophageal Adenocarcinoma	Open	Yes
2007-063		A Randomized Double-Blind Phase 3 Study Of Gemcitabine Plus AG-013736 Versus Gemcitabine Plus Placebo For The First-Line Treatment Of Patients With Locally Advanced Unresectable Or Metastatic Pancreatic Cancer	Open	Yes
2007-106		CP12-0710: An Open Label, Multicenter, Phase 2 Study Evaluating The Safety And Efficacy Of IMC-1121B As First-Line Monotherapy In Patients With Unresectable Hepatocellular Cancer	Open	Yes

<u><i>PIName</i></u>	<u><i>LCID</i></u>	<u><i>StudyName</i></u>	<u><i>StudyStatus</i></u>	<u><i>Open to Accrual</i></u>
2008-036		Phase I/II Study Of RAD001 In Combination With Temozolomide In Patients With Advanced Pancreatic Neuroendocrine Tumors	Open	Pending
2007-094		E1206/CALGB80403: Randomized Phase II Study Of ECF-C, IC-C, Or Folfox-C In Metastatic Esophageal And GE Junction Cancer	Open	Yes
<b><i>Christopher Tretter, M.D.</i></b>				
2008-016		E4805: A Randomized Phase II Study To Determine The Effect Of 2 Different Doses Of AVE0005 (VEGF Trap) In Patients With Metastatic Renal Cell Carcinoma	Open	Pending
2008-039		Neoadjuvant Chemotherapy Plus Nephroureterectomy For Locally Advanced Upper Tract Transitional Cell Cancer	Open	Yes
2008-014		S0421: Phase III Study Of Docetaxel And Atrasentan Versus Docetaxel And Placebo For Patients With Advanced Hormone Refractory Prostate Cancer	Open	Pending
2008-005		ECOG E3805: CHARTED: Chemohormonal Therapy Versus Androgen Ablation Randomized Trial For Extensive Disease In Prostate Cancer	Open	Yes
2007-110		CALGB 90203: Randomized Phase III Study Of Neo-Adjuvant Docetaxel And Androgen Deprivation Prior To Radical Prostatectomy Versus Immediate Radical Prostatectomy In Patients With High-Risk, Clinically Localized Prostate Cancer	Open	Yes
<b><i>John Wolff, M.D.</i></b>				
2004-070		NSABP-R-04: Clinical Trial Cmpg PreOP Radiation Therapy & Capecitabine With Or Without Oxaliplatin w/ PreOP Radiation Therapy & Continuous IV Infusion(CVI) Of 5Fluorouracil(5-FU) w/ or w/o Oxaliplatin In The Trtmnt Of Pts w/ Operable CarcinomaOf Rectum	Open	Yes
2004-089		An Open Label Single Arm Trial Of Immunotherapy With Autologous Antigen Presenting Cells Loaded With PA2024 (APC8015F) For Men With Objective Disease Progression On Protocol D9902 Part B/Protocol PB01	Open	Yes

<i><u>PIName</u></i>	<i><u>LCID</u></i>	<i><u>StudyName</u></i>	<i><u>StudyStatus</u></i>	<i><u>Open to Accrual</u></i>
2004-095		NSABP C-08: PH III Clinical Trial Cmprng Infusional 5-Fluorouracil(5-FU) Leucovorin & Oxaliplatin(mFOLFOX6) Evry Two Wks W/ Bevacizumab To Same Regimen Without Bevacizumab FR The Trtmnt Of Pts w/ Resected Stgs II & III Carcinoma Of The Colon	Open	No
2000-070		CALGB 99904: Phase III: Adjuvant Androgen Deprivation VS. Mitoxantrone Plus Prednisone Plus Androgen Deprivation In Selected High Risk Prostate Cancer Patients Following Radical Prostatectomy	Open	No
2004-048		Randomized Double Blind Placebo Controlled Ph III Trial Of Immunotherapy With Autologous Antigen Presenting Cells Loaded With PA2024(PROVENGE® APC8015) In Men With Metastatic Androgen Independent Prostatic Adenocarcinoma (D9902B)	Open	No
2007-029		RTOG 0522: A Randomized Phase III Trial Of Concurrent Accelerated Radiation And Cisplatin Versus Concurrent Accelerated Radiation, Cisplatin And Cetuximab(C225) [Followed By Surgery For Selected Patients] For Stage III And IV Head And Neck Carcinomas	Open	Yes
99-066		CALGB 89804: A Randomized PH III Trial Of Combinations Of Oxaliplatin(OXAL), 5-Fluorouracil(5-FU) And Irinotecan(CPT-11) As Initial Treatment Of Patients With Advanced Adenocarcinoma Of The Colon And Rectum	Open	No

### **Pulmonary & Critical Care Medicine**

*Count of Department Studies:* **10**

#### *John F. Beamis, Jr., M.D.*

2007-056		Bronchial Pre-Malignant Lesions Detection With The Use of Raman Probe Through The Flexible Bronchoscope(INVIVO Study)	Open	Yes
2006-019		Randomized, Phase IIB Trial Of Sulindac In Smokers With Bronchial Dysplasia	Open	Yes
2004-040		Evaluation Of The Pentax Safe 3000 Autofluorescence System In Relation To The Storz D-Light System	Open	Yes

#### *Anthony W. Gray, Jr., M.D.*

99-057		Cholesterol Plasma Levels In Surgical Critically Ill Patients	Open	Inactive
--------	--	---	------	----------

*PIName*      *LCID*      *StudyName*      *StudyStatus*      *Open to Accrual*

***David Neumeyer, M.D.***

2005-035      A Pilot Study Comparing At-Home Unattended Auto-CPAP Titration With In-The-Lab Attended CPAP Titration in Patients With Obstructive Sleep Apnea      Open      Yes

***David Riker, M.D.***

2007-115      Use Of Capnography As Surrogate Measure Of PC02 In Medical ICU Patients      Open      Yes

2008-007      A Pilot Study About Safety And Efficacy Of Atomized Intrapleural Lidocaine During Pleuroscopy      Open      Yes

2008-031      Pilot Study To Evaluate Optical Frequency Domain Imaging For Diagnosis Of Central Airway Disease      Open      Pending

2008-011      Safety And Efficacy Of Intravenous Dexmedetomidine Infusion During Flexible Bronchoscopy And Endobronchial Ultrasound (EBUS)      Open      Yes

***Andrew G. Villanueva, M.D.***

2006-067      MICU/CCU Palliative Medicine Quality Standards Of Care Database      Open      No

**Rheumatology**      *Count of Department Studies:*      **3**

***Tina Elias-Todd, M.D.***

2002-060      Rheumatoid Arthritis Treatment Evaluation Registry (RATER)      Open      No

2002-055      Genetic Polymorphisms In Wegner's Granulomatosis(WG)      Open      No

*S. Christine Kovacs, M.D.*

2000-010	A Multi-Cntr Rndmzd Dbl-Blind Placebo-Controlled Study Of The Human Anti-TNF Monoclonal Antibody Adalimumab In RA Pts Currently Receiving Treatment w/ Methotrexate Subtitle: Open-label Continuation Study of the Human Anti-TNF monoclonal antibo	Open	No
----------	--	------	----