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Revised Date: 8.19.2011				
PI	Protocol Name		Openings	Contact RN
Colon/Colorectal, Rectum, Supportive Care				
Early Stage Colon				
Bever / Chang (NSABP-P5)	Statin Polyp Prevention Trial in Patients with Resected Colon Cancer	Criteria: 1) Stage I/II colon adenocarcinoma, resected within 1 year. 2) Adjuvant therapy, if given, must be complete prior to enrollment. 3) No FAP/HNPCC, total colectomy/proctocolectomy; No hyperlipidemia with indication for statin therapy.	Many Openings	Valerie Sepeda 713-745-3670 / Diane Weber 713-563-5752
Treatment Naïve Metastatic Colorectal Cancer				
IMPORTANT: <ul style="list-style-type: none"> A lot of the studies listed below for met CRC require KRAS testing. KRAS is normal (Wildtype - WT) in 50%-70% of all metastatic colorectal pts (important for clinical trial purposes) <ul style="list-style-type: none"> If it is already not completed, pts can have it done here (using old slides or new biopsy) but it will take about 2 weeks to process. 				
Eng (SWOG C80405)	Phase III , FOLFOX or FOLFIRI with Bevacizumab and/or Cetuximab in Patients with Untreated Metastatic Colorectal Cancer <u>Two Arms</u> Arm A: FOLFOX or FOLFIRI + Bevacizumab; Arm B: FOLFIRI + Cetuximab; FOLFOX	Criteria: 1) No prior treatment for metastatic colorectal cancer, 2) Adjuvant therapy is OK if completed >12 months prior to recurrence. 2) Must have Wild-type(normal) KRAS[must have enough tissue for 1 H&E slide and a tissue block]	Only open at MDACC Katy satellite	Ritva Torma 713-794-1771
Previously Treated Metastatic Colorectal Cancer				
Overman (2009-0625)	Phase III , Study of Azacitidine & CAPOX in Metastatic CRC Patients Enriched for Hypermethylation of CpG Promoter Islands	Criteria: 1) Documented metastasis from colorectal adenocarcinoma 2) Must have progressed on treatment with either 5-FU or Capecitabine, plus Oxaliplatin (during or within 3 months of said treatment) 3) Patients taking coumarin-derivative anticoagulants are not eligible.	Many openings (Ph. II study)	Christine / 713-404-5448
Overman (2010-0378)	Phase II study of Second-Line Irinotecan plus Brivanib, a Dual Tyrosine Inhibitor of VEGFR and FGFR, in Metastatic Colorectal Cancer Patients Enriched for Elevated Levels of Plasma FGF Following Progression on Bevacizumab-based Treatment.	Criteria: 1) Progression on frontline chemo w/ bevacizumab, measurable lesions, ECOG 0-2. 2) Known bFGF level (within 12 weeks of bev treatment) 3) Adequate renal/hepatic/etc function 4)NO: brain mets, prior brivanib or irinotecan.	Many openings	Vicky / 713-792-4379 or 404-7988
Garrett (2009-0878)	Phase I Oral MK-2206 w/ AZD6244 w/ Locally Advanced or Metastatic Solid Tumors	Criteria: 1) Must have metastatic or locally advanced CRC that has failed to respond to standard therapy, or progressed despite standard therapy. 2) 1 assessable lesion per RECIST definition. 3) Must be able to swallow/absorb oral meds. 4) Pts w/ bradycardia (<50 bpm), bradyarrhythmia, or those on beta-blockers, non-dihydropyridine calcium channel blockers, or digoxin are not eligible.	No openings	Marie / 713-792-6515 or 606-3770

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Ravi (2004-0779)	Phase II , Randomized Trial of SIR-Spheres, Yttrium Microspheres with Cetuximab Plus Irinotecan for Patients with Advanced Colorectal Cancer Metastases to the Liver for KRAS WT patients	Criteria: 1) Adenocarcinoma of the colon or rectum, w/ at least one liver lesion that can be accurately measured 2) Documented disease progression within 6 months of the most recent dose of chemotherapy 3) Metastatic patients without local disease recurrence from colorectal cancer are still eligible.	Many Openings	Cynthia Brown/ 713-404-5989
Kopetz (2005-0842)	Phase II , FOLFOX + Cetuximab & Dasatinib in Metastatic Colorectal Cancer <u>Two Arms</u> 1) KRAS/BRAF wildtype(normal): FOLFOX+Dasatinib+Cetuximab 2) KRAS/BRAF mutant: FOLFOX+Dasatinib	Criteria: 1) Documented progression of disease after treatment with 5-FU, Oxaliplatin, and either Cetuximab or Panitumumab 2) Must have known KRAS/BRAF status, or have available tissue with which to test *NO limit to # of prior treatment regimens* *KRAS normal AND mutant are both eligible*	Many openings	Marie / 713-792-6515 or 606-3770
Garrett/Javle (2009-0956)	Phase 1 Oral ARRY-438162 in Patients with Advanced or Metastatic Biliary Cancer (Colorectal Cohort is open)	Criteria: 1) ECOG 0-1; <u>One</u> prior systemic therapy (including adjuvant). 2) Must agree to submission of archival tissue or be willing to undergo fresh biopsy. 3) Prior MEK inhibitor treatment excluded.	3 Openings (<u>BRAF-mutant only for colorectal cohort</u>)	Marie /713- 606-3770
Eng (2009-0990)	Phase III , Randomized, Placebo-Controlled Study of ARQ 197 in Combination with Irinotecan and Cetuximab in Subjects with Metastatic Colorectal Cancer with Wild-Type KRAS Who have Received Front-Line Systemic Therapy. (Ph. I now closed)	Criteria: 1) Inoperable, metastatic or recurrent colorectal cancer who have received at least 1 prior chemotherapy treatment (prior irinotecan allowed). 2) Must possess KRAS wild-type(normal) 3) Prior treatment must not have included an EGFR-inhibitor (cetuximab or panitumumab) 4) No prior cancers for at least 5 years	Many Openings	April / 713-745-2146 or 404-6954
Previously Untreated Rectal Cancer				
G. J. Chang (ACOSOG Z6051)	Phase III , Randomized controlled comparison of open versus laparoscopic total mesorectal excision for locally advanced rectal cancer following neoadjuvant chemoradiation.	Criteria: 1) Stage II/III rectal cancer 2) Patient must have preoperative chemoradiation therapy 3) Must agree to surgery within 8 weeks of chemoradiation	Many Openings	LaVerne Engerman/713-404-7577
Supportive Studies				
Kee (2008-0005)	Phase II , Randomized, Double Blind Comparison of CASAD vs. Placebo for the Treatment and Prevention of Diarrhea in Patients with Metastatic Colorectal Cancer	Criteria: 1) Patients with metastatic colorectal cancer who are scheduled to receive Irinotecan alone or in combination with 5-FU, and/or Cetuximab 2) No existing colostomy/ileostomy; no prior radiation/chemo within 4 weeks of beginning trial. No current radiation therapy *NO limit to # of prior treatment regimens*	Many Openings	Nancy Tang Pager: 713-606-0876/ Ext. 713-792-1485
Skibber (PCR05-0403)	*Non-Treatment Protocol* Multi-Institutional Colon/Rectal Cancer Outcomes Project Within NCCN	<i>Chart Review Protocol</i>	Many Openings	Lisa Inchani/ 713-606-3815 Nancy Burgess/ 606-3232

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<p><i>Eng/Cohen (2007-0825)</i></p>	<p>*Non-treatment Protocol* <i>Biobehavioral Effects of Qigong During Rectal Cancer Treatment</i></p>	<p>Criteria: 1)Stage II - III rectal cancer patients scheduled to undergo 6 wks preop chemoradiation followed by surgery; 2)Must be at least 18 yrs; must be able to read, speak, and write English; no major psychiatric diagnoses; no disabilities that would limit physical activity</p>	<p>Many Openings</p>	<p><i>Kayla Johnson 713-404-9432, Ideen Zeinali 713-606-1056,</i></p>
<p><i>Eng (2007-0769)</i></p>	<p>*Non-treatment Protocol* <i>Assessment of the Impact of Systemic Chemotherapy on the Quality of Life (QOL) in Patients with Metastatic Appendiceal Epithelial Neoplasms (AEN)</i></p>	<p>Criteria: 1)Must have metastatic appendiceal cancer 2)Must not be a candidate for surgery, and either never have received chemo, or be beginning a new regimen after disease progression on a prior treatment</p>	<p>1 Opening</p>	<p><i>Jonathan Phillips 713-606-2267 or 713-794-1843</i></p>
<p><i>Fogelman /Cleeland (2007-0637)</i></p>	<p>*Non-treatment Protocol* <i>Symptom Research Study: Prospective Study of Symptoms Related to Oxaliplatin-based Regimens in the Treatment of Colorectal Cancer</i></p>	<p>Criteria: 1)Treatment with an oxaliplatin-based regimen <i>Pt will be asked to do symptom questionnaires, cytokine analysis, and neurocognitive and neurosensory testing</i></p>	<p>Many Openings</p>	<p><i>Maggie Malekifar Ext 713-792-2054 Pager: 606-4379</i></p>