

## MEMORANDUM

**DATE:** September 30, 2008

**TO:** Southwest Oncology Group Members

**FROM:** Laurence Baker, Group Chair

**SUBJECT:** COMPLEXITY FUNDING PROGRAM

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A little more than a week ago at the annual Cooperative Group Chairs meeting with NCI leadership, it was announced that supplemental funds are being made available to 14 cooperative group trials that qualify based on their level of complexity. This funding is intended to more closely align reimbursement with trial complexity in accordance with the NCI's Clinical Trial Working Group (CTWG) Operational Efficiency Initiative. Representatives from the cooperative groups, including Marj Godfrey, SWOG Operations Director, and Anne Schott, SWOG Executive Officer along with others on the CTWG developed a simple, standardized model using ten criteria to establish complexity levels. This supplemental funding will provide up to an additional one thousand dollars per accrual and the program is effective retroactively to June 1, 2008. All SWOG members, including U-10 institutional members and CCOPs involved in the selected trials will participate; CCOPs are expected to receive 1.5 credits. The selection of high complexity trials will take place annually subject to the availability of funds. Some details of this new process are still being worked out.

- Two studies selected this year for complexity funding are SWOG trials, **S0518** a GI-carcinoid study and **S0337**, a GU superficial bladder cancer study
- Two more are intergroup studies **endorsed** by SWOG, CALGB-140503, a Lung NSCLC study, and CALGB-90203, a prostate cancer study.

The list of all 14 selected trials is attached. Feel free to contact my office if you have any questions. As soon as the details are finalized, funding memos will be updated and retro-active payments will be issued.

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**Group Chair's Office**

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Trial #	Title	Type	Lead Org	Lead Disease (CTEP Simple)	Activation Date
ACOSOG-Z1041	A Randomized Phase III Trial Comparing a Neoadjuvant Regimen of FEC-75 Followed by Paclitaxel Plus Trastuzumab with a Neoadjuvant Regimen of Paclitaxel Plus Trastuzumab Followed by FEC-75 Plus Trastuzumab in Patients with HER-2 Positive Operable Breast Cancer	Group	ACOSOG	Breast	7/2/2007
ACOSOG-Z6051	A Phase III Prospective Randomized Trial Comparing Laparoscopic-Assisted Resection Versus Open Resection for Rectal Cancer	Group	ACOSOG	GI - Rectal	8/15/2008
CALGB-140503	A Phase III Randomized Trial of Lobectomy Versus Sublobar Resection for Small (<= 2 cm) Peripheral Non-small Cell Lung Cancer	Group	CALGB	Lung - NSCLC	6/15/2007
CALGB-90203	A 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	Intergroup	CALGB	Prostate	12/15/2006
AAML0531	A Phase III Randomized Trial of Gemtuzumab Ozogamicin (Mylotarg®) Combined with Conventional Chemotherapy for De Novo Acute Myeloid Leukemia (AML) in Children, Adolescents, and Young Adults	Group	COG	Leukemia - AML	8/14/2006
E1900	A Phase III Trial in Adult Acute Myeloid Leukemia: Daunorubicin Dose-Intensification Prior to Risk-Allocated Autologous Stem Cell Transplantation	Intergroup	ECOG	Leukemia - AML	12/16/2002
E1A05	Lenalidomide (Revlimid®) - Dexamethasone (VRD) Versus Bortezomib (Velcade®) - Dexamethasone (VD) for Patients with Multiple Myeloma Who Have Completed a Dexamethasone Based Induction Regimen	Intergroup	ECOG	Myeloma	9/6/2007
GOG-0218	Plus Concurrent Bevacizumab (NSC #704865, IND #7921) Followed by Placebo, Versus Carboplatin and Paclitaxel Plus Concurrent and Extended Bevacizumab, in Women with Newly Diagnosed, Previously Untreated, Stage III or IV Epithelial Ovarian or Primary Peritoneal and	Intergroup	GOG	Gyn - Ovary	9/26/2005
GOG-0213	Combination with Bevacizumab (NSC #704865, IND #7921) Followed by Bevacizumab and Secondary Cytoreductive Surgery in Platinum-Sensitive, Recurrent Ovarian, Peritoneal Primary and Fallopian Tube Cancer. NCI-Supplied Agents: Bevacizumab (NSC#704865, IND#7921)	Group	GOG	Gyn - Ovary	12/6/2007
N0577	Phase III Intergroup Study of Radiotherapy versus Temozolomide Alone versus Radiotherapy with Concomitant and Adjuvant Temozolomide for Patients with Newly Diagnosed Anaplastic Oligodendroglioma or Anaplastic Mixed Glioma with Chromosomal Co-deletions of 1p and 19q	Intergroup	NCCTG	Brain - Anaplastic oligodendro-glioma	TBA this year
NSABP-B-40	Breast Cancer Evaluating the Effect on Pathologic Complete Response (pCR) of Adding Capecitabine or Gemcitabine to Docetaxel when Administered Before AC with or without Bevacizumab and Correlative Science Studies Attempting to Identify Predictors of High	Intergroup	NSABP	Breast	11/20/2006
RTOG-0534	A Phase III Trial of Short Term Androgen Deprivation with Pelvic Lymph Node or Prostate Bed Only Radiotherapy (SPORT) in Prostate Cancer Patients with a Rising PSA After Radical Prostatectomy	Group	RTOG	GU - Prostate	2/13/2008
S0518	Phase III Prospective Randomized Comparison of Depot Octreotide Plus Interferon Alpha Versus Depot Octreotide Plus Bevacizumab (NSC #704865) in Advanced, Poor Prognosis Carcinoid Patients	Group	SWOG	GI - Carcinoid	12/1/2007
S0337	A Phase III Blinded Study of Immediate Post-TURBT Instillation of Gemcitabine Versus Saline in Patients With Newly Diagnosed Or Occasionally Recurring Grade I/II Superficial Bladder Cancer	Group	SWOG	GU - TCCA urothelial tract	7/15/2007
<b>14 Trials:</b>					
	<b>Breast - 2 Trials</b>				
	<b>Brain - 1 Trial</b>				
	<b>GI - 2 Trial (Carcinoid &amp; Rectal)</b>				
	<b>Gyne - 2 Trials (Ovary)</b>				
	<b>GU - 3 Trial (2 Prostate &amp; 1 Urothelial Tract)</b>				
	<b>Leukemia - 2 Trials (AML - 1 Adult &amp; 1 Peds)</b>				
	<b>Lung - 1 Trial (NSCLC)</b>				
	<b>Myeloma - 1 Trial</b>				