

Scientific Steering Committee Concept Review Sheet (2006 - January 2012)

Coperative Group/ Document Number	Phase	Status	Document Name	Principal Investigator	Date Received in PIO (for SC evaluation)	Date Original Reviewed in SC	Date of Re-Review in SC (if applicable)	Date Protocol Approved by NCI	Date Protocol Open to Accrual/ Status/ Accrual Total as of 1/31/12	BIQSFP Assay/Test/Tool
BREAST CANCER STEERING COMMITTEE (BCSC)										
NCIC CTG MA.32	3	Revised & Resubmit; APPROVED	A Phase III Randomized Trial of the Effect of Metformin versus Placebo on Recurrence and Survival in Early Stage Breast Cancer	Pam Goodwin, MD	3/25/2009; 07/14/2009 (rev)	4/23/2009	7/23/2009	3/26/2010	6/25/2010 [1254]	Fatigue, Behavioral, and Health Outcomes
ECOG E2108	3	Revised & Resubmit; APPROVED	A Randomized Trial of the Value of Early Local Therapy for the Intact Primary Tumor in Women with Metastatic Breast Cancer	Seema Khan, MD	4/30/2009	6/16/2009	N/A	In Review 11/30/2009	2/8/2011 [17]	
NSABP 8708 (NSABP B-48)	3	Pending with Revisions; Revise & Resubmit; APPROVED	A Randomized Phase III Clinical Trial Evaluating Pathologic Complete Response in Patients with Palpable and Operable, Triple-Negative Breast Cancer Treated with Docetaxel and Cyclophosphamide Followed by Gemcitabine and Carboplatin with or without the PARP1 Inhibitor BSI-201	Steven A. Limentani, MD	10/28/2009	11/19/2009	2/17/2010	In Review 6/30/2010		
SWOG S1007	3	APPROVED; Revised & Resubmit;	A Phase III, Randomized Clinical Trial of Standard Adjuvant Endocrine Therapy +/- Chemotherapy in Patients with 1-9 Positive Nodes, Hormone-responsive and HER2-negative Breast Cancer according to Recurrence Score (RS)	Ana Maria Gonzalez-Angulo, MD	2/24/2010; 5/25/2010 (rev)	3/18/2010	6/16/2010	1/3/2011	01/15/2011 [436]	OncoType DX
RTOG 1005	3	APPROVED; Revised & Resubmit;	A Phase III Trial of Accelerated Whole Breast Irradiation with Hypofractionation plus Concurrent Boost Versus Standard Whole Breast Irradiation with Conventional Fractionation plus Sequential Boost for Early-Stage Breast Cancer	Frank A. Vicini, MD, FACR	7/22/2010 10/13/2010 (rev)	8/18/2010	10/20/2010	5/2/2011	5/24/2011 [50]	
ACOSOG Z11103	2 & 3	APPROVED; Pending with Revision;	ALternate approaches for clinical stage II and III Estrogen Receptor positive breast cancer NeoAdjuvant Treatment (ALTERNATE) Study	Cynthia X. Ma, MD, PhD	3/30/2011; 5/23/2011 (rev 1); 06/08/211 (rev 2)	4/20/2011	6/15/2011			Ki67
RTOG 1119	2	APPROVED (With recommendations)	Phase II Randomized Study of Whole Brain Radiotherapy in Combination With Concurrent Lapatinib in Patients with Brain Metastasis From HER2-Positive Breast Cancer – A Collaborative Study of RTOG and KROG	In Ah Kim, MD, PhD	8/8/2011	9/15/2011	N/A			
NSABP #9186	3	APPROVED: Pending with Revisions	A Phase III Clinical Trial Comparing the Combination of Docetaxel Plus Cyclophosphamide to Anthracycline-Based Regimens for Women with Node-Positive or High-Risk Node-Negative, HER2-Negative Breast Cancer	Patrick J. Flynn, MD	9/28/2011	10/19/2011	12/21/2011			
SWOG S1207	3	APPROVED (with Recommendations)	Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer	Mariana Chavez Mac Gregor, MD, MSc	12/27/2011	1/19/2012	N/A			
BRAIN MALIGNANCY STEERING COMMITTEE (BMSC)										
COG ACNS1022	2	Pending Review; APPROVED	A Phase II Trial of Lenalidomide in Pediatric Patients with Recurrent, Refractory or Progressive Low-Grade CNS Gliomas	Kathy Warren, MD	12/27/2010	1/13/2011	3/10/2011	In Review 08/19/2011		
PBTC C9073 (PBTC-03)	2	Pending Review; APPROVED	A Feasibility and Phase II Study of ABT888, an oral poly(ADP-ribose) polymerase inhibitor, and concurrent radiation therapy, followed by ABT888 and temozolomide, in children with newly diagnosed high-grade or diffuse pontine gliomas (DIPG)	Jack Meng-Fen Su, MD	05/04/2011 (rev1)	3/10/2011	5/12/2011	In Review 08/31/2011	11/17/2011 [0]	
COG ACNS1123	2	Pending Review; APPROVED (with Recommendations)	Phase 2 Trial of Response-Based Radiation Therapy for Patients with Localized Central Nervous System Germ Cell Tumors	Ute Bartels, MD	5/25/2011; 8/31/2011	7/14/2011	9/8/2011			
RTOG 1125	2 & 3	Pending Review; APPROVED	Phase II/III Randomized, Double Blinded Placebo Controlled Trial Comparing Adjuvant Temozolomide and Ipilimumab with Adjuvant Temozolomide in Patients with Newly Diagnosed Glioblastoma After Successful Completion of Concurrent Radiation and Temozolomide	Mark R. Gilbert, MD	7/20/2011; 10/06/2011 (rev)	8/11/2011	10/13/2011			

Scientific Steering Committee Concept Review Sheet (2006 - January 2012)

Coperative Group/ Document Number	Phase	Status	Document Name	Principal Investigator	Date Received in PIO (for SC evaluation)	Date Original Reviewed in SC	Date of Re-Review in SC (if applicable)	Date Protocol Approved by NCI	Date Protocol Open to Accrual/ Status/ Accrual Total as of 1/31/12	BIQSFP Assay/Test/Tool
CLINICAL IMAGING STEERING COMMITTEE (CISC)										
CALGB 71101	3	APPROVED	Change in Mammographic Density with Metformin Use: A Companion Study to NCIC study MA.32	Jennifer Eng-Wong, MD, MPH	7/25/2011	8/9/2011	N/A			
#9175 [ACRIN-6698]	3	APPROVED	MR Imaging Biomarkers for Assessment of Breast Cancer Response to Neoadjuvant Treatment: A sub-study of the I-SPY 2 TRIAL (Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging And moLecular Analysis)	Nola Hylton, PhD.	8/15/2011	9/13/2011	N/A			
GYNECOLOGIC CANCER STEERING COMMITTEE (GCSC)										
GOG 0213	3	Pending with Revisions; APPROVED	A Phase 3 Randomized Controlled Clinical Trial of Carboplatin and Paclitaxel Alone or in Combination with Bevacizumab Followed by Bevacizumab or in Combination with Bevacizumab Followed by Bevacizumab and Erlotinib and Secondary Cytoreductive Surgery in Platinum-Sensitive, Recurrent Ovarian and Peritoneal Primary Cancer	Robert L. Coleman, MD	10/26/04; revision 1 - 6/14/05; revision 2 - 7/5/05; 8/16/06	9/28/2006	1/9/2007	10/19/2007	12/6/2007 [685]	
GOG 0238	2	APPROVED	A Randomized Trial of Pelvic Irradiation with or without Concurrent Weekly Cisplatin In Patients with Pelvic-Only Recurrence of Carcinoma of the Uterine Corpus	Higinia R. Cardenes, MD, PhD	NOT A CONCEPT; Study came to PIO as Protocol; 12/12/2006	2/23/2007	N/A	5/11/2007	2/25/2008 [41]	
GOG UC-0704 (GOG-0258)	3	APPROVED	A Randomized Phase III Trial of Cisplatin and Tumor Volume Directed Irradiation Followed by Carboplatin and Paclitaxel vs. Carboplatin and Paclitaxel for Optimally Debulked, Advanced Endometrial Carcinoma	Daniela Matei, MD	5/29/2007	7/9/2007	N/A	6/29/2009	6/29/2009 [327]	
GOG LOI 8093 (GOG-0248)	2	APPROVED	Randomized Phase II Trial of Temsirolimus or the Combination of Hormonal Therapy Plus Temsirolimus in Women with Advanced or Recurrent Endometrial Carcinoma	Gini Fleming, MD	Not a CONCEPT; LOI; 4/6/2007	5/8/2007	N/A	7/28/2008	9/29/2008 [Closed to Accrual] [73]	
GOG-0204R-CVM-0704 (GOG-0240)	3	APPROVED	A Randomized Phase III Trial of Cisplatin plus Paclitaxel with and without Bevacizumab versus the Non-Platinum Doublet, Topotecan plus Paclitaxel, with and without Bevacizumab, in Stage IVB, Recurrent or Persistent Carcinoma of the Cervix	Krishnansu S. Tewari, MD	NOT A CONCEPT; Protocol; 05/31/07	6/25/2007	N/A	11/21/2008	4/6/2009 [Closed to Accrual & Treatment] [399]	
UC-0701 (GOG-0261)	3	APPROVED	Randomized Phase III Trial of Carboplatin plus Paclitaxel versus Ifosfamide plus Taxol in Patients with Advanced, Persistent or Recurrent Carcinosarcoma (Mixed Mesodermal Tumors) of the Uterus	Matthew A. Powell, MD	7/31/2007	8/7/2007	N/A	7/23/2009	8/17/2009 [254]	
UC-0604 (2007) (GOG-0249)	3	APPROVED	Phase III Trial of Pelvic Radiation Therapy versus Vaginal Cuff Brachytherapy Followed by Paclitaxel/Carboplatin Chemotherapy in Patients with High Risk, Early Stage Endometrial Cancer	Scott McMeekin, MD	08/21/06; 10/09/07 (rev)	11/6/2007	N/A	12/1/2008	3/23/2009 [386]	PROMIS 7 (HRQL)
OVM0606	3	Approved - WITHDRAWN BY GOG 4/1/08; COMPANY WITHDREW SUPPORT	A Randomized Phase III Trial of Neoadjuvant Carboplatin/ Paclitaxel vs. Carboplatin/Weekly Abraxane in Performance Status Challenged and Geriatric Patients	Thomas J. Herzog, MD	N/A - sent directly to Ovarian TF	11/6/2007	N/A	N/A	W/D	
DTM0708	2	Approved; WITHDRAWN BY GOG	A Randomized Phase II Evaluation of Volociximab (M200) plus Weekly Paclitaxel vs. Weekly Paclitaxel Alone in the Third-line Treatment of Recurrent or Persistent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer (GOG-0186 series)	Linda A. Duska, MD	N/A - sent directly to Uterine TF	9/11/2007	N/A	N/A	W/D	
GOG OVM0705 (GOG-0252)	3	APPROVED	Phase III Clinical Trial of Bevacizumab with IV versus IP Chemotherapy in Ovarian, Fallopian Tube and Primary Peritoneal Carcinoma	Joan L. Walker, MD	12/14/2007	1/8/2008	N/A	7/20/2009	7/27/2009 [Closed to Accrual] [1560]	
RTOG 0724	3	Pending with Revisions; APPROVED	Phase III Randomized Study of Concurrent Chemotherapy and Pelvic RT with or Without Adjuvant Chemotherapy in High-Risk Patients with Early-Stage Cervical Carcinoma Following Radical Hysterectomy	Anuja Jhingran, MD	9/25/2007; 3/24/2009	6/9/2008	9/9/2008	8/10/2009	9/16/2009 [33]	
GOG OVM0703 (GOG-0255)	3	APPROVED	A Randomized Phase III Trial in Patients with Epithelial Ovarian, Fallopian Tube, or Peritoneal Cancer with a Polyvalent Vaccine-KLH Conjugate + QS-21 versus QS-21	Paul Sabbatini, MD	4/22/2008	5/13/2008	N/A	2/19/2009	7/26/2010 [62]	

Scientific Steering Committee Concept Review Sheet (2006 - January 2012)

Coperative Group/ Document Number	Phase	Status	Document Name	Principal Investigator	Date Received in PIO (for SC evaluation)	Date Original Reviewed in SC	Date of Re-Review in SC (if applicable)	Date Protocol Approved by NCI	Date Protocol Open to Accrual/ Status/ Accrual Total as of 1/31/12	BIQSFP Assay/Test/Tool
GOG 0241	3	Revised and Submitted; APPROVED;	A Randomized Phase III Evaluation of Capecitabine and Oxaliplatin (Xelox) versus Carboplatin and Paclitaxel in Mucinous Adenocarcinoma of the Ovary	David M. Gershenson, MD	01/04/08; 04/16/08 (rev); 12/30/08 (rev); 02/04/10 (rev)	5/13/2008	1/20/2009	9/8/2010	10/12/2010 [4]	
GOG DTM0720 (GOG-0250)	2b	APPROVED	Randomized Phase IIB Evaluation of Gemcitabine-Docetaxel with or without Bevacizumab for Advanced or Recurrent Uterine Leiomyosarcoma	Martee L. Hensley, MD	2/25/2008; 03/17/2006 (rev)	4/7/2008	N/A	10/19/2009	11/9/2009 [72]	
GOG CVM0801 (GOG 0263)	3	APPROVED	Randomized Clinical Trial for Adjuvant Chemo-radiation in Post-operative Cervical Cancer Patients with Intermediate Risk Factors	Sang Young Ryu, MD	03/26/08; 04/24/08 (rev); 01/30/09 (rev)	2/17/2009	N/A	4/1/2010	4/12/2010 [48]	
GOG RTM0602 (GOG 0264)	2b	Pending with Revisions/ APPROVED	A Phase II Trial of Paclitaxel and Carboplatin vs. Bleomycin, Etoposide, and Cisplatin for Newly Diagnosed Advanced Stage Sex Cord-Stromal Tumors of the Ovary	Jubilee Brown, MD	4/28/2009	5/19/2009	??	12/29/2009	2/8/2010 [5]	
DTM0801 (GOG - 0186G)	2	APPROVED	A Randomized Phase II Evaluation of Oral Everolimus (RAD001) plus Bevacizumab vs. Oral Placebo plus Bevacizumab in the Treatment of Recurrent or Persistent Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer	William P. Tew, MD	8/7/2008; 10/28/08 (rev)	11/18/2008	N/A	4/6/2009	12/27/2010 [51]	
SWOG S0904	2	APPROVED	Randomized Phase II Study of Docetaxel Followed by ZD6474 (Vandetanib) vs. Docetaxel plus ZD6474 in Patients with Persistent or Recurrent Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Carcinoma	Robert L. Coleman, MD	8/19/2008; 10/28/2008 (rev)	11/18/2008	N/A	3/17/2009	3/15/2010 [Closed to Accrual] [131]	
OVM0813 (GOG 0262)	3	Pending with Revisions; APPROVED	A Randomized Phase III Trial of Every-Three-Weeks versus Dose Dense Weekly Paclitaxel and Carboplatin plus Concurrent Bevacizumab in the Treatment of Primary Suboptimal Stage III or IV Epithelial Ovarian, Primary Peritoneal or Fallopian Tube Carcinoma	John K. Chan, MD	11/10/2008; 3/10/2009 (rev)	12/1/2008	1/20/09, 3/17/09, 4/7/09	7/2/2010	9/27/2010 [Temporarily Closed to Accrual] [528]	
DTM0905 (GOG - 0186I)	2	APPROVED	A Randomized Phase II Evaluation of Single Agent Bevacizumab (NSC #704865) and Combination Bevacizumab with Fosbretabulin in the Treatment of Persistent or Recurrent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Carcinoma	Bradley J. Monk, MD	9/29/2009	10/20/2009	N/A	2/22/2011	3/21/2011 [12]	
NCIC CTG OV.21	3	APPROVED	A Phase II/III study of intraperitoneal (IP) plus intravenous (IV) chemotherapy versus IV carboplatin plus paclitaxel in patients with epithelial ovarian cancer optimally debulked at surgery following neoadjuvant intravenous chemotherapy	Helen Mackay, MD	11/9/2009	11/17/2009	N/A	11/1/2010	9/11/2009 [51]	
SWOG S0903	2	APPROVED; WITHDRAWN BY SWOG 9-2-10 (SWOG GYN committee closed)	Randomized Phase II Study Evaluating Carboplatin/Paclitaxel Compared with Carboplatin/Paclitaxel and Everolimus in Patients with Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer in First Relapse	Lainie P. Martin, MD	3/29/2010	4/20/2010	N/A	In Review 07/29/2010	W/D	
CVM1004 (ANZGOG-0902; GOG-0274)	3	Pending with Recommendations; APPROVED	A Phase III Trial of Adjuvant Chemotherapy Following Chemoradiation as Primary Treatment for Locally Advanced Cervical Cancer Compared to Chemoradiation Alone: GOG COLLABORATION WITH THE OUTBACK TRIAL (ANZGOG 0902)	Kathleen Moore, MD	3/30/2010 7/2/2010 (rev)	4/20/2010	7/20/2010	7/22/2011	1/9/2012 [0]	
DTM1003 (GOG-0186J)	2b	APPROVED	A Randomized Phase IIB Evaluation of Pazopanib versus Weekly Paclitaxel plus Pazopanib versus Weekly Paclitaxel in the Treatment of Persistent or Recurrent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Carcinoma	Debra L. Richardson, MD	6/15/2010	7/20/2010	N/A	In Review 03/29/2011	12/12/2011 [0]	
GOG DTM0929	2	Approved; WITHDRAWN BY GOG	A Phase II Study Of The Potent, Highly Selective Poly(Adp-Ribose) Polymerase (Parp) -1 And -2 Inhibitor Mk-4827 In The Treatment Of Persistent Or Recurrent High-Grade Serous Ovarian Cancer	Robert L. Coleman, MD	10/21/2010	11/16/2010	N/A	N/A	W/D	
GOG 0270		Pending with Revision; APPROVED	Groningen International Study on Sentinel Nodes in Vulvar Cancer (Groinss-V) II: An Observational Study	Brian M. Slomovitz, MD	11/24/2010 05/10/11 (rev)	1/18/2011	5/31/2011	In Review 09/28/2011	1/3/2012 [0]	
GOG UC1009	3	Pending with Revision; APPROVED	A Phase III Randomized Trial of Gemcitabine plus Docetaxel followed by Doxorubicin v. Letrozole for Early Stage High Grade Uterine Leiomyosarcoma	Martee L. Hensley, MD	3/23/2011; 06/22/2011 -(rev)	4/19/2011	7/12/2011	2/6/2012		

Scientific Steering Committee Concept Review Sheet (2006 - January 2012)

Coperative Group/ Document Number	Phase	Status	Document Name	Principal Investigator	Date Received in PIO (for SC evaluation)	Date Original Reviewed in SC	Date of Re-Review in SC (if applicable)	Date Protocol Approved by NCI	Date Protocol Open to Accrual/ Status/ Accrual Total as of 1/31/12	BIQSFP Assay/Test/Tool
GOG UC1005	3	APPROVED	A Phase III Randomized Trial of Pulse Actinomycin-D versus Multi-day Methotrexate for the Treatment of Low-risk Gestational Trophoblastic Neoplasia	Julian C. Schink, MD	4/28/2011	5/17/2011	N/A	2/8/2012		
GASTROINTESTINAL CANCER STEERING COMMITTEE (GISC)										
RTOG 0436	3	Pending with Revisions; APPROVED	A Phase III Trial Evaluating the Addition of Cetuximab to Paclitaxel, Cisplatin and Radiation for Patients with Locally Advanced Esophageal Cancer	Mohan Suntharalingam, MD	09/20/06 (rev); 12/12/06 (rev2)	10/16/2006	12/18/2006	10/27/2007; 12/11/2007	6/30/2008 [287]	
ACOSOG Z6051	3	Pending with Revisions; APPROVED	A Phase III Trial Comparing Laparoscopic-Assisted Rectal Resection (LARR) to Open Resection for Rectal Cancer	James Fleshman, MD	4/2/2007	5/21/2007	7/16/2007	7/22/2008	8/15/2008 [353]	
USMCI 8214	3	APPROVED	A Phase III Trial Comparing Best Available Systemic Therapy to Cytoreduction + Hyperthermic Intraperitoneal Mitomycin-C + Best Available Systemic Therapy in Patients with Limited Peritoneal Dissemination of Colon Adenocarcinoma	Alex Stojadinovic, MD, Jesus Esquivel, MD	12/5/2007	12/17/2007	N/A	7/7/2010	8/23/2010 [Closed to Accrual & Treatment] [1]	
CALGB 80701	2	Pending with Revisions/ APPROVED	A Phase II Randomized Study of Temozolomide or Temozolomide + Bevacizumab in Patients with Advanced Pancreatic Neuroendocrine Tumors	Matt Kulke, MD	12/3/2007; 05/12/08 (rev)	12/17/2007	5/19/2008	In Review 2/19/2009	10/15/2010 [72]	
CALGB 80802	3	Pending with Revisions/ APPROVED	Phase II/III Randomized Study of Sorafenib plus Doxorubicin Versus Sorafenib in Patients with Advanced Hepatocellular Carcinoma (HCC)	Abou-Alfa Ghassan, MD	4/10/2008; 08/07/08 (rev)	5/19/2008	8/18/2008	11/2/2009	2/15/2010 [81]	
ECOG E1208	3	Pending with Revisions/ APPROVED	A Phase III Randomized Trial of Chemoembolization with or without Sorafenib in Unresectable Hepatocellular Carcinoma (HCC) in Patients with and without Vascular Invasion.	John Kauh, MD	5/27/2008; 6/9/2008 (rev); 9/8/2007 (rev)	6/16/2008	9/15/2008	10/5/2009	10/28/2009 [70]	
CALGB 80702	3	Pending with Revisions/ APPROVED	A 2 x 2 Phase III Trial of Celecoxib and Vitamin D in Addition to Standard Chemotherapy for Stage III Colon Cancer	Jeffrey A. Meyerhardt, MD	7/7/2008, 10/13/2008, 2/21/2009	7/21/2008	11/17/2008 and 2/27/2009	6/15/2010	6/22/2010 [441]	
RTOG 0848	3	Pending with Revisions/ APPROVED	Gemcitabine, With and Without Erlotinib, Followed By a Second Randomization With and Without Chemoradiation, as Adjuvant Treatment For Pancreatic Head Cancer: A Phase III RTOG/SWOG/NCIC/EORTC Study	Ross Abrams, MD	8/8/2008; 11/10/2008	8/18/2008	11/17/2008	10/23/2009	11/17/2009 [122]	
NSABP 8358 (NSABP-C-11)	3	Pending with Revisions/ APPROVED	Phase III Trial Evaluating the Role of Perioperative Chemotherapy and Bevacizumab in Patients with Potentially Resectable Hepatic Colorectal Metastases	Michael Choti, MD	12/22/2008; 04/13/09 (rev)	1/26/2009	4/20/2009	7/29/2010	8/23/2010 [Administratively Complete] [6]	
ECOG E7208	2	Pending with Revisions/ APPROVED	A Randomized Phase II Study of Irinotecan with Cetuximab Plus/Minus IMC-1121B in Metastatic Colorectal Cancer Patients Progressing on Bevacizumab-Containing Chemotherapy	Howard S. Hochster, MD	2/3/2009	2/27/2009	5/18/2009	2/22/2010	10/8/2010 [13]	
RTOG 1010	3	Pending Review; APPROVED	A Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of HER2 Overexpressing Esophageal Adenocarcinoma	Howard Safran, MD	09/25/2009; 10/23/2009 (rev)	11/16/2009	1/11/2010	8/11/2010	12/30/2010 [80]	HER2
NCCTG N0949	3	Revised and Resubmitted; APPROVED	Randomized Phase III Trial of mFOLFOX7 Plus Bevacizumab Versus 5-Fluorouracil or Capecitabine Plus Bevacizumab as First-line Treatment in Elderly Patients (≥75 Years Old) with Metastatic Colorectal Cancer	Alex Grothey, MD	3/29/2010	4/19/2010	6/21/2010	12/23/2010	01/21/2011 [9]	

Scientific Steering Committee Concept Review Sheet (2006 - January 2012)

Coperative Group/ Document Number	Phase	Status	Document Name	Principal Investigator	Date Received in PIO (for SC evaluation)	Date Original Reviewed in SC	Date of Re-Review in SC (if applicable)	Date Protocol Approved by NCI	Date Protocol Open to Accrual/ Status/ Accrual Total as of 1/31/12	BIQSFP Assay/Test/Tool
CALGB 80803	2	Pending with Revisions APPROVED	Phase II Trial of PET Scan-Directed Combined Modality Therapy in Esophageal Cancer	Kathryn A. Goodman, MD	4/20/2010	6/21/2010	8/16/2010	4/4/2011	7/15/2011 [2]	central pathology & PET/CT
NCCTG N1048/ CALGB 81001/ ACOSOG Z6092	2/3	Pending with Revisions; APPROVED	A Phase II/III trial of Neoadjuvant FOLFOX, with Selective Use of Combined Modality Chemoradiation versus Preoperative Combined Modality Chemoradiation for Locally Advanced Rectal Cancer Patients Undergoing Low Anterior Resection with Total Mesorectal Excision	Deborah Schrag MD (CALGB) , Alessandro Fichera (ACOSOG) Robert McWilliams Mayo Clinic (NCCTG)	1/20/2011	2/28/2011	4/4/2011	10/14/2011	1/13/2012 [0]	
CALGB 81003	2	APPROVED	Phase IB/Randomized Phase II Study of Folfirinox plus AMG-479 or placebo in Patients with Previously Untreated, Metastatic Pancreatic Adenocarcinoma	Brian M. Wolpin, MD, MPH	2/17/2011	3/28/2011	N/A	In Review 08/01/2011	11/4/2011 [0]	
SWOG S1115	2	Pending with Revisions; APPROVED	Randomized Phase II Clinical Trial of AZD-6244 and MK-2206 vs. mFOLFOX in Patients with Metastatic Pancreatic Cancer after Prior Chemotherapy	Vincent Chung, MD	6/1/2011	7/18/2011	8/15/2011			
SWOG S1201	2	APPROVED	A Randomized Phase II Pilot Study Prospectively Assigning Treatment for Patients Based on ERCC1 for Advanced/Metastatic Gastric Cancer or Gastroesophageal (GE) Junction Cancer	Syma Igbal, MD	6/27/2011	8/15/2011	N/A			ERCC-1
RTOG 1112	2 & 3	Pending with Revisions; APPROVED	Randomized Phase II/III Study of Sorafenib versus Sorafenib and Stereotactic Body Radiation Therapy in Hepatocellular Carcinoma	Laura A. Dawson, MD	7/25/2011; 10/07/2011 (rev)	8/15/2011	10/17/2011			
CALGB 81103	2	APPROVED	Prospective Randomized Phase II Trial of Pazopanib Versus Placebo in Patients with Progressive Carcinoid Tumors	Emily Bergsland, MD	12/13/2011	1/30/2012	N/A			
GENITOURINARY CANCER STEERING COMMITTEE (GUSC)										
RTOG 0815	3	Pending with Revisions/ APPROVED	A Phase III Prospective Randomized Trial of Dose-Escalated Radiotherapy With or Without Short-Term Androgen Deprivation Therapy for Patients With Intermediate-Risk Prostate Cancer	Alvaro A. Martinez, MD	7/11/08 11/7/08	8/20/2008	11/19/2008	6/18/2009	9/14/2009 [504]	
CALGB 90802	3	APPROVED	Randomized Phase III Trial Comparing Everolimus Plus Placebo versus Everolimus Plus Bevacizumab for Advanced Renal Cell Carcinoma Progressing After Treatment with Tyrosine Kinase Inhibitors.	George K. Philips, MD	7/21/2008	9/17/2008	N/A	8/19/2010	9/15/2010 [30]	
CALGB 90901	3	Pending with Revisions; APPROVED; WITHDRAWN	A Randomized Phase III Study of ixabepilone, mitoxantrone and prednisone versus mitoxantron and prednisone alone in patients with castration resistant prostate cancer previously treated with docetaxel chemotherapy	Charles Ryan, MD	4/1/2009	6/17/2009	8/19/2009	No Protocol	W/D	
SWOG S0931	3	APPROVED	EVEREST: EVErolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study	Christopher Ryan, MD	4/3/2009	5/20/2009	N/A	3/15/2010	4/1/2011 [79]	
SWOG S1011	3	Approved	Prospective Evaluation Of The Benefit Of A Standard Versus An Extended Pelvic Lymphadenectomy Performed At Time Of Radical Cystectomy For Bladder Cancer With Adjuvant Chemotherapy Administration For Node Positive Disease	Seth Paul Lerner, MD	3/31/2010	4/21/2010	N/A	09/30/2010; 01/07/2011 (rev)	8/1/2011 [4]	
RTOG 0924	3	Pending with Revisions; Approved	Androgen Deprivation Therapy and High Dose Radiotherapy With or Without Whole-Pelvic Radiotherapy in Unfavorable Intermediate or Favorable High Risk Prostate Cancer: A Phase III Randomized Trial	Mack Roach III, MD	6/2/2010; 10/14/2010 (rev)	7/21/2010	10/20/2010	5/24/2010	7/7/2011 [34]	
ECOG E2810	3	Pending with Revisions; APPROVED (On HOLD)	Randomized, double-blind phase III study of pazopanib vs. placebo in subjects with metastatic renal cell carcinoma who have no evidence of disease following metastasectomy	Leonard J. Appleman, MD, PhD	3/30/2011; 6/8/2011 (rev)	4/20/2011	7/20/2011			
RTOG 1115	3	APPROVED	Phase III Trial of Dose Escalated Radiation Therapy and Standard Androgen Deprivation Therapy (ADT) with a GnRH Agonist vs. Dose Escalated Radiation Therapy and Enhanced ADT with a GnRH Agonist and TAK-700	M. Dror Michaelson, MD	2/14/2011	5/4/2011	N/A	In Review 09/30/2011		

Scientific Steering Committee Concept Review Sheet (2006 - January 2012)

Cooperative Group/ Document Number	Phase	Status	Document Name	Principal Investigator	Date Received in PIO (for SC evaluation)	Date Original Reviewed in SC	Date of Re-Review in SC (if applicable)	Date Protocol Approved by NCI	Date Protocol Open to Accrual/ Status/ Accrual Total as of 1/31/12	BIQSFP Assay/Test/Tool
HEAD & NECK CANCER STEERING COMMITTEE (HNSC)										
RTOG 0920	3	APPROVED	Phase III Randomized Study of Adjuvant Intensity-Modulated Radiotherapy With Versus Without Cetuximab in Patients With Locally Advanced Resected Squamous Cell Carcinoma of the Head and Neck	Mitchell Machtay, MD	1/9/2008; 5/8/2008	2/1/2008	5/5/08 and 8/4/08	7/22/2009	11/5/2009 [125]	
ACRIN 6685 (#8270)	N/A	Pending with Revisions; APPROVED	FDG PET/CT Staging of Head and Neck Cancer and its Impact on the NO Neck	Val Lowe, MD	4/30/2008	11/3/2008	2/23/2009	9/2/2009	4/1/2010 [67]	
RTOG 1008	2	APPROVED	A Randomized Phase II Study of Adjuvant Concurrent Chemotherapy and Radiation in Resected High-Risk Malignant Salivary Gland Tumors	Cristina P. Rodriguez, MD; David Adelstein, MD	2/1/2010	5/3/2010	N/A	9/17/2010	11/3/2010 [8]	
RTOG 1016	2/3	Pending with Revisions; APPROVED	Phase II-III Trial of Moderate De-Escalation of Chemotherapy and Radiation in Favorable Risk, Locally Advanced, HPV-Associated Oropharynx Cancer	Andy Trotti, MD	3/22/2010	4/12/2010	7/12/2010	2/15/2011	6/9/2011 [54]	p16
LEUKEMIA CANCER STEERING COMMITTEE (LKSC)										
CALGB 11002	2	APPROVED	A Randomized Phase II Trial of Decitabine-based Induction Strategies for Patients ≥ 60 Years Old with Acute Myeloid Leukemia	Gail J. Roboz, MD	6/24/2010; 9/20/2010 (Rev)	7/27/2010	9/28/2010	In Review 6/3/2011	11/16/2011 [0]	
SWOG S1117	2	APPROVED	A Randomized Phase II Study of Azacitidine in Combination with Lenalidomide vs. Azacitidine in Combination with Vorinostat vs. Azacitidine Alone for Higher-Risk Myelodysplastic Syndromes (MDS)	Mikael A. Sekeres, MD	6/8/2011	6/28/2011	N/A	1/20/2012		
LYMPHOMA CANCER STEERING COMMITTEE (LYSC)										
ECOG E1410	2	WITHDRAWN; Approved	Intergroup Randomized Phase 2 Three-Arm Study In Patients ≥ 60 With Previously Untreated Mantle Cell Lymphoma Of Therapy With: Arm A = Rituximab+ Bendamustine (R – B), Arm B = Rituximab + Bendamustine + Bortezomib (R - B – V), or Arm C = Rituximab + Bendamustine Followed By Lenalidomide + Rituximab Consolidation (R - B → L – R)	Mitchell Smith, MD, PhD	9/1/2010	10/8/2010	N/A	N/A	W/D	
SWOG S1001	2	Revise & Resubmit; APPROVED	A Phase II Trial of PET-directed Therapy for Early Stage Diffuse Large B-cell Lymphoma	Daniel O. Persky, MD	10/6/2010; 01/24/2011	12/10/2010	2/11/2011	5/16/2011	7/18/2011 [2]	
ECOG E2410	2	APPROVED	Phase II Trial of Response-Adapted Therapy Based on Positron Emission Tomography (PET) for Bulky Stage I and II Classical Hodgkin Lymphoma (HL)	Ranjana Advani, MD	1/21/2011	2/11/2011	N/A	6/21/2011		
SWOG S1106	2	APPROVED	A Randomized Phase II Trial of R-HCVAD-MTX/ARA-C Induction Followed by Consolidation With an Autologous Stem Cell Transplant vs. R-Bendamustine Induction Followed by Consolidation With an Autologous Stem Cell Transplant for Previously Untreated Patients ≤ 65 Years of Age With Mantle Cell Lymphoma	Steven H. Bernstein, MD	1/28/2011	3/11/2011	N/A	7/29/2011	10/1/2011 [0]	
ECOG E1411 [formerly ECOG E1410]	2	APPROVED	Intergroup Randomized Phase 2 Four Arm Study In Patients ≥ 60 With Previously Untreated Mantle Cell Lymphoma Of Therapy With: Arm A = Rituximab+ Bendamustine Followed By Rituximab Consolidation (RB → R); Arm B = Rituximab + Bendamustine + Bortezomib Followed By Rituximab Consolidation (RBV → R), Arm C = Rituximab + Bendamustine Followed By Lenalidomide + Rituximab Consolidation (RB → LR) or Arm D = Rituximab + Bendamustine + Bortezomib Followed By Lenalidomide + Rituximab Consolidation (RBV → LR)	Mitchell Smith, MD, PhD	2/18/2011	3/11/2011	N/A	7/29/2011		
CALGB 51101		APPROVED	Randomized trial of myeloablative versus non-myeloablative consolidation chemotherapy for newly diagnosed primary CNS B-cell lymphoma	Tracey Batchelor, MD	5/23/2011	7/8/2011	N/A	12/27/2011		
MYELOMA CANCER STEERING COMMITTEE (MYSC)										
ECOG E1A10	2	APPROVED	A Randomized Selection Phase II Study of Rituximab, Bortezomib, and Dexamethasone and Rituximab, RAD001, and Dexamethasone in Previously Untreated, Symptomatic Waldenström's Macroglobulinemia	Leonard T. Heffner, Jr.	5/13/2010; 5/28/2010	7/6/2010	9/7/2010	5/27/2011	7/20/2011 [0]	

Scientific Steering Committee Concept Review Sheet (2006 - January 2012)

Coperative Group/ Document Number	Phase	Status	Document Name	Principal Investigator	Date Received in PIO (for SC evaluation)	Date Original Reviewed in SC	Date of Re-Review in SC (if applicable)	Date Protocol Approved by NCI	Date Protocol Open to Accrual/ Status/ Accrual Total as of 1/31/12	BIQSFP Assay/Test/Tool
PEDIATRIC LEUKEMIA AND LYMPHOMA STEERING COMMITTEE (PLLSC)										
COG ANHL1131		Pending Revision; APPROVED (with Recommendations)	Intergroup Trial for Children or Adolescents with B-cell Non-Hodgkin Lymphoma (NHL) or Mature B-cell Leukemia (B- AL): Evaluation of Rituximab Efficacy and Safety in High Risk Patients.	Thomas G. Gross, MD, Ph.D	4/29/2011; 7/22/2011	6/3/2011	8/5/2011			
PEDIATRIC AND ADOLESCENT SOLID TUMOR STEERING COMMITTEE (PASTSC)										
COG ANBL1122	2	APPROVED (on hold); WITHDRAWN	Phase II Randomized Trial of Irinotecan/Temozolomide with Temsirolimus or Bevacizumab (Avastin) in Children with Relapsed Neuroblastoma	Rajen Mody, MD, MS	6/29/2011	7/25/2011	N/A	N/A	W/D	
COG ADVL1122	2	APPROVED (with recommendations)	A Phase II Trial of Pazopanib (NSC# 737754, IND# 75648) in Children with Refractory Solid Tumors	Alice Lee, MD	8/19/2011	9/26/2011	N/A			
COG ANBL1221	2	APPROVED (with recommendations)	Phase II Randomized Trial of Irinotecan/Temozolomide with Temsirolimus or Chimeric 14.18 Antibody (ch14.18) in Children with Relapsed/Refractory Neuroblastoma	Rajen Mody, MD, MS	1/5/2012	1/23/2012	N/A			
SYMPTOM MANAGEMENT & QUALITY OF LIFE STEERING COMMITTEE (SxQOL)										
NCCTG N08C3	3	APPROVED	Phase III Double-Blind, Placebo Controlled Study of Gabapentin for the Treatment of Delayed CINV (Chemotherapy Induced Nausea and Vomiting) in Patients Receiving Highly or Moderately Emetogenic Chemotherapy	Deborah Barton, RN, PhD	2/12/2008	3/11/2008	N/A	1/28/2009	4/17/2009 [Closed to Accrual] [430]	
WFU-08-03-06	2	Revise/Resubmit; APPROVED	Phase II Randomized Placebo Controlled Study of Armodafinil on Fatigue in Brain Tumor Patients Receiving Brain Radiation Therapy	Edward G. Shaw, MD	3/12/2008	4/8/2008	7/8/2008	12/3/2009	8/5/2010 [45]	
NCCTG N08C7	3	APPROVED	Phase III, Randomized, Placebo-controlled, Double-Blind Trial of Flaxseed for the Treatment of Hot Flashes	Deborah Barton, RN, PhD	5/14/2008	6/10/2008	N/A	5/27/2009	10/9/2009 [Closed to Accrual & Treatment] [210]	
WFU-08-08-08	2	Revise/Resubmit; APPROVED	Yoga during Breast Cancer Treatment: Establishing Community-Based Partnerships	Suzanne Danhauer, PhD	8/18/2008	9/9/2008	1/13/2009	6/22/2009	10/21/2009 [Closed to Accrual] [40]	
WFU-08-08-09	2	Revise/Resubmit/ APPROVED	A Randomized Phase II Dose Finding Study of ArginMax with or without Phosphodiesterase-5 Inhibitors for Its Effect on Erectile Function and Quality of Life in Survivors of Prostate Cancer Previously Treated with Radiotherapy	James Urbanic, MD	8/14/2008	9/9/2008	2/10/2009	3/26/2010	10/18/2010 [72]	
Moffit Research Base HLMCC-0806	2	Revise/Resubmit/ APPROVED	Phase II Placebo-controlled Trial of Lisinopril and Coreg CR to Reduce Cardiotoxicity in Patients with Breast Cancer Receiving (neo)Adjuvant Chemotherapy with Trastuzumab (Herceptin)	Maya Guglin, MD	8/25/2008	10/14/2008	1/13/2009	8/31/2009	3/1/2010 [65]	
NCCTG N08CB	3	Revise/Resubmit/ APPROVED	A Phase III Randomized, Placebo-Controlled, Double-Blind Study of Intravenous Calcium/Magnesium in Two Different Versions to Prevent Oxaliplatin-Induced Sensory Neurotoxicity	Charles Loprinzi, MD	9/12/2008	10/14/2008	1/13/2009	3/29/2010	6/22/2010 [242]	
GOG 0257	3	Revise/Resubmit/ APPROVED	A Randomized, Double-Blind, Placebo Controlled Trial Using Acetyl L-Carnitine (ALCAR) for the Prevention of Chemotherapy-Induced Peripheral Neuropathy in Patients with Recurrent Ovarian, Primary Peritoneal or Fallopian Tube Cancer	David Kushner, MD	9/26/2008	11/18/2008	4/14/2009	12/6/2011		
URCC 09005	2	Revised & Resubmit; APPROVED	Curcumin for the Prevention of Radiation-Induced Dermatitis in Breast Cancer Patients	Juli Ryan, MD, MPH	2/19/2009	4/14/2009	12/8/2009	10/25/2010	10/25/2010 [544]	
SWOG S0927	2	Revise & Resubmit; APPROVED	Randomized Placebo-Controlled Trial of Omega-3-Fatty Acid for the Control of Aromatase Inhibitor-Induced Musculoskeletal Pain in Women with Early Stage Breast Cancer	Dawn Hershman, MD, MS	4/3/2009	5/12/2009	11/10/2009	10/4/2010		
NCCTG N09C6	3	Revise & Resubmit; APPROVED	Phase III Double-Blind Cross-over Study of Doxepin Rinse versus Placebo in the Treatment of Acute Oral Mucositis Pain in Patients Receiving Radiotherapy and/or Chemotherapy	James L. Leenstra MD; Robert C. Miller, MD	7/24/2009	9/8/2009	12/8/2009	6/9/2010	12/17/2010 [84]	
RTOG 1012	2	APPROVED	Phase II Randomized Dose Seeking Trial of the Prophylactic Use of Manuka Honey for the Reduction of Chemoradiation Therapy Induced Esophagitis During the Treatment of Lung Cancer	Lawrence B. Berk, MD	10/20/2009	12/8/2009	N/A	11/23/2010		
RTOG 0938	2	Revise & Resubmit; APPROVED	A Randomized Phase II Trial of Hypofractionated Radiotherapy for Favorable Risk Prostate Cancer	Jean-Paul Bahary, MD	3/8/2010; 8/18/2010 (rev)	4/20/2010	9/14/2010	11/23/2010	9/29/2011 [0]	
NCCTG N10C1	3	Approved	Vaginal DHEA for Vaginal Dryness: A Phase III Randomized, Double Blind, Placebo-Controlled Study	Debra Barton MD	5/7/2010	5/11/2010	N/A	5/18/2011	7/29/2011 [68]	
NCCTG N10C2	3	Revise & Resubmit ; APPROVED	Phase III Double-Blind, Placebo-Controlled Study of Magnesium Supplements to Reduce Menopausal Hot Flashes	Haeseong Park, MD, MPH	8/12/2010; 3/3/2011 (rev 1)	9/14/2010	3/8/2011	9/1/2011	9/30/2011 [5]	
WFU 10-05-16	2	APPROVED	A Feasibility Study of Donepezil in Breast Cancer Survivors with Chemotherapy-Related Self-Reported Cognitive Dysfunction	Julia Lawrence, DO	5/12/2010	8/10/2010	N/A	10/18/2011		

Scientific Steering Committee Concept Review Sheet (2006 - January 2012)

Coperative Group/ Document Number	Phase	Status	Document Name	Principal Investigator	Date Received in PIO (for SC evaluation)	Date Original Reviewed in SC	Date of Re-Review in SC (if applicable)	Date Protocol Approved by NCI	Date Protocol Open to Accrual/ Status/ Accrual Total as of 1/31/12	BIQSFP Assay/Test/Tool
NCCTG N10CB	3	Revise & Resubmit; APPROVED	A Phase III, Randomized, Double-Blind Placebo Controlled Study of the Probiotic Preparation VSL#3® versus Placebo in the Prevention of Acute Radiation Enteritis in Patients Receiving Abdominal and/or Pelvic Radiation Therapy	Robert C. Miller MD & Christopher L. Hallemeier, MD	12/20/2011; 3/16/2011 (rev)	1/11/2011	4/12/2011	10/31/2011		
NCCTG N10C7	2 / 3	Revise & Resubmit; APPROVED	A Randomized Double-blind Placebo Controlled, Phase II/III, Study of Aromatase Inhibitors and Transdermal Testosterone in the Adjuvant Treatment of Postmenopausal Women with Aromatase Inhibitor Induced Arthralgiass	Stephen Birrell, MD, PhD	1/14/2011; 06/13/2011	3/8/2011	7/12/2011	2/2/2012		
NCCTG N10C3-A	3	Revise & Resubmit; APPROVED	The Use of Armodafinil (Nuvigil) To Reduce Severe Cancer-Related Fatigue in Patients with Glioblastoma Multiforme: A Randomized, Novel Adaptive Design Study.	Charles Loprinzi, MD	4/29/2011; 8/26/2011	6/14/2011	10/11/2011			
NCCTG N11C5	3	APPROVED	Phase III, Randomized, Double-Blind Study of Lactobacillus brevis CD2 Lozenges versus Placebo in the Prevention of Acute Oral Mucositis in Patients with Head and Neck Cancer Receiving Concurrent Radiotherapy and Chemotherapy	Charles Loprinzi, MD	8/31/2011	10/11/2011	N/A			
SWOG S1202	3	APPROVED	Phase III Study of Duloxetine for Treatment of Aromatase Inhibitor-Associated Musculoskeletal Symptoms in Women with Early Stage Breast Cancer	Norah L. Henry, MD, PhD	11/1/2011	12/13/2011	N/A			
RTOG 1203	3	APPROVED	A Randomized Phase III Study of Three-Dimensional vs. IMRT Pelvic Radiation for Endometrial and Cervical Cancer (TIME-C)"	Ann Klopp, MD, PhD	11/28/2011	1/24/2012	N/A			
THORACIC MALIGNANCY STEERING COMMITTEE (TMSC)										
RTOG 0937	3 (original) 2 (final)	Pending with Revisions/ APPROVED	Randomized Phase II Study Comparing Prophylactic Cranial Irradiation Alone to Prophylactic Cranial Irradiation and Consolidative Extra-Cranial Irradiation for Extensive Disease Small Cell Lung Cancer (ED-SCLC)	Elizabeth Gore, MD	5/7/2009 7/30/2009	5/21/2009	8/20/2009	1/12/2010	3/18/2010 [19]	
RTOG 1021 (formerly ACOSOG Z4099)	3	APPROVED	A Randomized Phase III Study of Sublobar Resection versus Stereotactic Body Radiation Therapy in High Risk Patients with Stage I Non-Small Cell Lung Cancer (NSCLC)	Hiran C. Fernando, MD (ACOSOG); and Robert Timmerman, MD (RTOG)	2/22/2010	3/18/2010	N/A	4/11/2011	5/2/2011 [4]	
RTOG 1106	2	Pending Review ; APPROVED	Randomized Phase II Trial of Individualized Adaptive Radiation Using During-Treatment FDG-PET/CT and Modern Radiation Technology to Dose Escalate in Locally Advanced Non-Small Cell Lung Cancer (NSCLC)	Feng Ming (Spring) Kong, MD, PhD	1/4/2011; 4/14/2011 (rev1);	2/17/2011	5/5/2011	In Review 07/08/2011		
ACOSOG Z41102	3	APPROVED	Personalized Adjuvant Therapy In Patients With Completely Resected Non-small Cell Lung Cancer (NSCLC)	Ramaswamy Govindan, MD	3/29/2011	5/5/2011	N/A			
ECOG E2511	2	Pending Review; APPROVED	Phase II Randomized Double Blind Clinical Trial of Cisplatin and Etoposide in Combination with Veliparib (ABT-888) or Placebo as Frontline Therapy for Extensive Stage Small Cell Lung Cancer	Taofeek K. Owonikoko, MD, PhD	7/20/2011; 10/17/2011 (rev)	8/18/2011	11/10/2011			