Southwest
Oncology Group
A National Clinical Research Group

December 1, 2004

TO: ALL SOUTHWEST ONCOLOGY GROUP MEMBER, CCOP, UCOP AND AFFILIATE MEDICAL ONCOLOGISTS, SURGEONS, RADIATION ONCOLOGISTS, PATHOLOGISTS, SURGEONS AND CLINICAL RESEARCH ASSOCIATES; ECOG, CALGB, NCIC-CTG, NCCTG, RTOG, COG, ACOSOG, NSABP, CTSU AND EPP

FROM: Charles A. Coltman, Jr., M.D. - Chairman

RE: GUIDANCE ON REPORTING ADVERSE EVENTS TO INSTITUTIONAL REVIEW BOARDS FOR NIH-SUPPORTED MULTICENTER CLINICAL TRIALS (http://grants.nih.gov/grants/guide/notice-files/not99-107.html)

MEMORANDUM

All Southwest Oncology Group Phase III studies are monitored by our Data and Safety Monitoring Committee (DSMC). The Group policy regarding the function and composition of the DSMC is Policy #21 - which may be found on the public portion of the Group web site at http://swog.org/Visitors/download/policies/Policy21.pdf Copies of this document should be made available to local Institutional Review Boards (IRBs).

As outlined in the "GUIDANCE ON REPORTING ADVERSE EVENTS TO INSTITUTIONAL REVIEW BOARDS FOR NIH-SUPPORTED MULTICENTER CLINICAL TRIALS (http://grants.nih.gov/grants/guide/notice-files/not99-107.html)", the NIH requires that summary reports of adverse events be communicated from the DSMC to the IRBs at participating institutions. The interim reports for Southwest Oncology Group studies are posted in the Report of Studies area on the members side of the Group web site at https://swog.org/. This site also contains the deliberations of the DSMC from their most recent meetings. A copy of the deliberations from the 10/21/04 meeting is attached. The information from these reports should be made available to your IRB.

If the DSMC has decided to make recommendations resulting in substantial changes to a study, those changes will be circulated in the form of a protocol amendment or a special notification (e.g., "Dear Physician" letter).

PC/dbs

Enclosure

cc: John J. Crowley, Ph.D.
Elaine Armstrong, M.S.
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M E M O R A N D U M

TO: Dr. Coltman and Data and Safety Monitoring Committee:
Drs. Boyett, Crowley, Kempin, Korn, Langer, MacDonald, Martin, Minasian, Petrylak, Thomas Jr. and Ms. Stewart

FROM: John Crowley, PhD

DATE: November 1, 2004

RE: SWOG DSMC – Minutes of SWOG Data and Safety Monitoring Committee Meeting of Thursday, October 21, 2004

1. Accrual
   a. Breast / Cancer Control S0230 – A Phase III Trial of LHRH Analog During Chemotherapy to Reduce Ovarian Failure Following Standard Adjuvant Chemotherapy for Early Stage Hormone-Receptor Negative Breast Cancer. Other Groups, and in particular the International Breast Cancer Study Group, are joining this trial, with the promise of greatly increased accrual. The DSMC will look at accrual again in one year.
   b. GYN S0200 – A Phase III Randomized Study of Pegylated Liposomal Doxorubicin Plus Carboplatin Versus Carboplatin in Platinum-Sensitive Patients with Recurrent Epithelial Ovarian or Peritoneal Carcinoma After Failure of Initial Platinum-Based Chemotherapy. Accrual to this trial should be terminated, since accrual has not increased sufficiently to guarantee successful completion of the study.

2. Closure, Publication Plan, Sample Size Amendment
   a. Breast / Cancer Control S9630 – A Randomized Comparison of MPA and Observation for Prevention of Endometrial Pathology in Post-Menopausal Breast Cancer Patients Treated with Tamoxifen. This trial has reached its goal of eligible patients and should be closed to accrual.
   b. Lung S9900 – A Randomized Phase III Trial of Surgery Alone or Surgery Plus Preoperative Paclitaxel/Carboplatin in Clinical Stage IB (T2N0), II (T1-2N1, T3N0) and Selected IIIA (T3N1) Non-Small Cell Lung Cancer (NSCLC). Reports at ASCO in 2004 demonstrated an improvement in survival with adjuvant chemotherapy compared to surgical controls, and the trial was closed. A request to prepare an abstract of the results of this study for ASCO 2005 was approved, provided the abstract did not contain survival data.

c. Lung S0023 – A Phase III Trial of Cisplatin/Etoposide/RT with Consolidation Docetaxel Followed by Maintenance Therapy with Gefitinib or Placebo in Patients with Inoperable Locally Advanced Stage III Non-Small Cell Lung Cancer. Accrual to the randomized step of this trial has been slower than anticipated, and an amendment to lower the sample size from 672 to 600 randomized patients, requiring 4 more years of accrual, was approved in principle. The investigators are encouraged to study the reasons for the lower than expected randomization rate and to take any appropriate action.
d. GU / Cancer Control S9917 – L-Selenium-Based Chemoprevention of Prostate Cancer among Men with High Grade PIN. An amendment to increase the sample size to account for a possibly lower conversion rate from PIN to prostate cancer was discussed, but was deferred until data from this trial give evidence of the conversion rate. A request to process serum samples for selenium levels by arm, as a compliance measure, was approved with the provision that the DSMC needs to approve any presentation or publication of these data.

3. Interim Analyses
   a. Brain S0001 – A Phase III Study of RT and BCNU +- O6BG for Newly Diagnosed Glioblastoma Multiforme and Gliosarcoma. A careful review of toxicity on the O6BG arm revealed no reason for safety concerns, and the trial should continue.
   b. Lymphoma S9704 – A Randomized Phase II Trial Comparing Chemo/RT and Autologous Stem Cell Transplant to CHOP-R for Patients with High-Intermediate and High Risk (IPI) Diffuse Aggressive NHL. A formal interim analysis revealed no reason for stopping the trial early, so the study should proceed as planned.

The following trials were reviewed by mail, not discussed at the meeting, and should proceed with no change:

Breast
S0012
S0221
S0226

Genitourinary
S9346
S9921

HN
S9908

Leukemia
S0106
S0325

Lung
S0124

Lymphoma
S0016

Melanoma
S0008

The next meeting is scheduled for Thursday, April 7, 2005 at 5 pm at the Hyatt Regency Denver.

JC:mdb

CC: Drs. Alberts, Liu, Gandara, Pisters, Bunn, Kelly, Albain, Lippman, Moore, Potkul, Ankerst, Barlow, Crawford, Marshall, Tangen, Pisters, Livingston, Blumenthal, Fisher, Stiff, LeBlanc; Ms Rankin