Southwest
Oncology Group
A National Clinical Research Group

June 15, 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, 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 4/29/04 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.
Dana B. Sparks, M.A.T.
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Southwest Oncology Group

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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: June 1, 2004

RE: SWOG DSMC – Minutes of SWOG Data and Safety Monitoring Committee Meeting of Thursday, April 29, 2004

1. Accrual
   a. 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 monitored, and the trial will be closed unless there is a substantial increase in accrual in the next six months.
   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 and the IASLC meetings in Vancouver in 2003 (IALT) demonstrated a small improvement in survival with adjuvant chemotherapy compared to surgical controls. Accrual has slowed, possibly as a result. There will be two new reports at ASCO 2004 in June of adjuvant trials. The committee agreed with the investigators in the trial that the rationale for this study should be assessed after the results of the trials presented at ASCO are known, and the committee will review any major proposed changes.
   c. Lymphoma 9438 – Total Body Irradiation, Etoposide, Cyclophosphamide and Autologous Peripheral Blood Stem Cell Transplantation Followed by Randomization to Therapy with Interleukin-2 versus Observation for Patients with Non-Hodgkin's Lymphoma. This study has almost reached its accrual goal, and with accrual at a standstill, the committee voted to close the trial and publish the results after the protocol-specified follow-up is complete.
2. Interim Analyses
   a. GU S9346 – Intermittent Androgen Deprivation in Patients with Stage D2 Prostate Cancer. Results from the first formal interim analysis revealed no reason to stop the trial early, so the committee voted for continuance with no changes. In addition, a request for release of data to investigate the relationship of PSA to outcome, without using treatment assignment, was approved.

b. Lung S0023 – A Phase III Trial of Cisplatin/Etoposide/Radiotherapy with Consolidation Docetaxel Followed by Maintenance Therapy with ZD 1839 or Placebo in Patients with Inoperable Locally Advanced Stage III Non-Small Cell Lung Cancer. Results from the first formal interim analysis revealed no reason to stop the trial early, so the committee voted for continuance with no changes.

The following studies were reviewed by mail but not discussed at the meeting and are to continue unchanged:

Brain
S0001

Breast
S9630
S0012
S0221
S0230

Gastrointestinal
S0205

Genitourinary
S9917
S9921

HN
S9908

Lung
S0124

Lymphoma
S9704
S0016

Melanoma
S0008

The next meeting is scheduled for Thursday, October 21, 2004 at 5 pm at the Hyatt Regency Crown Center, Kansas City, Missouri.

JC:mdb

CC: Drs. Albain, Alberts, Ankerst, Bearman, Crawford, Gandara, Green, Gritz, Liu, Livingston, Markman, Marshall, Pisters, Tangen

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"Premature disclosure of confidential Data and Safety Monitoring Committee interim therapeutic results on SWOG by members of the Data Monitoring Committee will result in censure of that member by the Board of Governors. Censure options will include immediate loss of authorship in the study presentation and publication, decertification of status as a current and future Study Coordinator, and/or removal from leadership in the disease committee of record."