Southwest
Oncology Group
A National Clinical Research Group

January 15, 2003

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 10/25/02 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.
Nickey McCasland, R.N., M.P.H.
Marjorie A. Godfrey

M E M O R A N D U M

TO: 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 12, 2002

RE: Minutes of SWOG Data and Safety Monitoring Committee Meeting
Friday October 25, 2002

1. Minutes
   The minutes of the April 2002 meeting should be changed to reflect an accrual expectation of 10 patients per month, not per week, for GU study S9921.

2. Accrual
   a. Brain S0001 -- BCNU/RT +- O6BG for Gliobastoma (also toxicity). The two toxic deaths on O6BG arm have been fully investigated by the study team, and were likely the result of the entry of ineligible or marginal patients. The eligibility criteria have been tightened to avoid this. There have been no toxic deaths on this arm in the last 6 months. Accrual has improved to 50-60 per year and the study should continue.
   b. GU/Cancer Control S9917 -- Selenium vs Placebo for Patients with High Grade PIN. Accrual has improved to over 100 per year, and the rate of randomization for those entered is much higher than planned. An amendment is being prepared to allow for only one (10-12 core) biopsy for eligibility, rather than two 6-core biopsies. These developments and changes make successful completion of the study likely, and the trial should continue.
   c. Melanoma S0008 -- High Dose Interferon vs Combination Chemotherapy + Interferon for High Risk Disease (also rationale for the study). The Melanoma Committee reviewed recent data regarding the tenability of the hypotheses underpinning this trial, both for the high dose interferon control and the biochemotherapy experimental arm, and is convinced there is still ample justification for this trial. Accrual has improved and CALGB is just now joining. The study should continue.

3. Data Requests
    a. GU 9346 -- Intermittent vs Continuous Combined Androgen Deprivation in Advanced Prostate Cancer. Use of data from the time of induction (blinded to the randomized maintenance treatment code) to study possible racial differences in outcome was approved.
    b. GU S9916 – Estramustine/Docetaxel vs Mitoxantrone/Prednisone for Advanced, Hormone Refractory Disease. Release of data for planning purposes to Dr. Crawford was approved.

4. Amendments
    a. Lymphoma S0016 – CHOP +- Two Variations for Follicular NHL. An amendment to drop the CHOP arm and make this a two arm trial with new statistical considerations was approved by fax ballot in August and this decision was reaffirmed.
    b. Lymphoma S9704 – High Dose Chemotherapy and Autologous Stem Cell Support vs CHOP for Diffuse Aggressive NHL. A proposal to add Rituxan to the pre-randomization induction phase of the trial was tabled pending a request to the ECOG DSMC for information regarding E4494 that could shed light on the desirability of this amendment.

5. Interim Analyses
    a. Lung S0003 – Carbo/Taxol +- Tirapazamine for Advanced Nonsmall Cell. At this first formal interim analysis, the hypothesis that adding Tirapazamine to Carbo/Taxol adds benefit with acceptable risk was judged to be untenable, and the study should close.
    b. Lymphoma 9438 – IL-2 vs Observation after High Dose Therapy in Patients after High Dose Therapy in NHL. This is the second formal interim analysis. The study should continue to the next planned interim analysis, at full planned accrual, which should be in approximately 30 months.

The next meeting is scheduled for Thursday, April 10, 2003 at 5 pm at the Hyatt Regency San Diego.

JC:ls

CC: Drs. Blumenthal, Spence, Barger, Crawford, Marshall, Lippman, Sondak, Flaherty, Hussain, Fisher, Thompson, Press, Gandara, Wiliamson, Tangen, Pauler, Liu, LeBlanc; Ms Rankin