Southwest
Oncology Group
A National Clinical Research Group

January 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, 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 10/2/03 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

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Statistical Center
Fred Hutchinson Cancer Research Center
1100 Fairview Avenue North, MP-557
Seattle, Washington 98109-4417
Phone: 206/667-4623
FAX 206/667-4408

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: October 10, 2003

RE: SWOG DSMC – Minutes of SWOG Data and Safety Monitoring Committee Meeting of Thursday, October 2, 2003

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 S0002 – Smoking Cessation for Patients with Stage I-II Non-Small Cell Lung Cancer. The Committee heard that the American College of Surgeons Oncology Group has agreed to join this study, but that other extensive changes, including a broadening of the eligibility requirements to include other tumor types, will be necessary for this trial to succeed in its goals. The Committee felt that a completely new trial was being discussed, and recommended that the current trial be closed.
2. External Evidence
    a. GU S9917 – L-Selenium-Based Chemoprevention of Prostate Cancer Among Men with High Grade Prostatic Intraepithelial Neoplasia. A recent report in the Journal of the National Cancer Institute indicates that there may be an increase in non-melanoma skin cancer associated with the use of selenized yeast. The consent form should be modified to include this information.

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). A recent report as ASCO and the IASLC meetings in Vancouver demonstrated a small improvement in survival with adjuvant chemotherapy compared to surgical controls. The Committee agreed with the investigators in the trial that this was one study among many, some negative, some positive, and that the design of this study (neo-adjuvant chemotherapy vs surgical control) was still relevant, with no changes in consent necessary.

3. Interim Analyses
   a. Breast S9623 – A Comparison of Intensive Sequential Chemotherapy using Doxorubicin plus Paclitaxel plus Cyclophosphamide with High Dose Chemotherapy and Autologous Hematopoietic Progenitor Cell Support for Primary Breast Cancer in Women with >= 4 Involved Axillary Lymph Nodes, Phase III, Intergroup. A formal interim analysis revealed that the hypothesis of an improvement with high dose therapy was untenable, and that these negative findings should be published without further follow-up.

The next meeting is scheduled for Thursday, April 29, 2004 at 5 pm at the Hyatt Regency Huntington Beach (California).

JC:mdb

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