Southwest
Oncology Group
A National Clinical Research Group

December 1, 2008

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

FROM: Laurence H. Baker, D.O. - 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)

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**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 must 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 October 31, 2008 meeting is attached. The information from this report must 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: Cathy M. Tangen, Dr.P.H.
Nathan Erickson
Elaine Armstrong, M.S.
Dana B. Sparks, M.A.T.
Nickey McCasland, R.N., M.P.H.
Kati M. Laszlo, M.S.B.A.
Marjorie A. Godfrey

**Southwest Oncology Group**

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**Statistical Center**
Fred Hutchinson Cancer Research Center
1100 Fairview Avenue North, M3-C102
Seattle, Washington 98109-1024
Phone: 206/667-4623
FAX 206/667-4408

# M E M O R A N D U M

**TO:** Southwest Oncology Group Data & Safety Monitoring Committee Members

**FROM:** Cathy Tangen, DrPH

**DATE:** November 4, 2008

**RE:** SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting of Friday, October 31, 2008

1. Request to DSMC to Monitor a Trial
   A Clinical Trial of Helicobacter Pylori Eradication in Latin America. The SWOG DSMC has agreed to serve as the monitoring committee of record for this pilot trial.

2. Data Request
   Genitourinary S9921 – Adjuvant Androgen Deprivation Versus Mitoxantrone Plus Prednisone Plus Androgen Deprivation in Selected High Risk Prostate Cancer Patients Following Radical Prostatectomy. A request to analyze and report time to testosterone recovery on both arms, and to report primary and secondary outcome rates on the control arm of this study has been granted.

3. Accrual
   Leukemia S0521 – A Randomized Trial of Maintenance Versus Observation for Patients with Previously Untreated Low and Intermediate Risk Acute Promyelocytic Leukemia, Phase III. This study has had very slow accrual since its activation on June 1, 2007, although the DSMC recognizes that the Leukemia Committee has a proven record of successfully conducting trials in this population. We anticipate accrual will increase, and we will review the study again at our spring 2009 meeting.

4. Genitourinary S0337 – Immediate Post-TURBT Instillation of Gemcitabine Versus Saline in Patients with Newly Diagnosed or Occasionally Recurring Grade I/II Superficial Bladder Cancer. Accrual has been slow for this trial, which opened on July 15, 2007. An amendment is being drafted to address some logistical issues regarding upper tract imaging, and drug distribution issues are also being resolved. We expect accrual to improve, and this study will be reviewed again in spring 2009.

5. Interim Analysis
   Lymphoma S9704 – A Randomized Phase III Trial Comparing Early High Dose Chemoradiotherapy and an Autologous Stem Cell Transplant to Conventional Dose

"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."

CHOP Chemotherapy and Rituximab (for CD20+ Patients) for Patients with Diffuse Aggressive Non-Hodgkin's Lymphoma in the High-Intermediate and High Risk Groups of the International Classification Prognostic Groups. No statistical boundaries have been crossed. The study should continue as planned.

6. Study Closure
   Genitourinary/CC S0437 – PCPT Companion Long Term Follow Up for Men Diagnosed with Prostate Cancer. The DSMC recognizes that this study will close after the completion of the DNA collection. This will most likely occur within the 2008 calendar year.

7. Safety Monitoring
   Leukemia S0106 – A Phase III Study of the Addition of Gemtuzumab Ozogamicin Induction Therapy versus Standard Induction with Daunomycin and Cytosine Arabinoside Followed by Consolidation and Subsequent Randomization to Post-Consolidation Therapy with Gemtuzumab Ozogamicin or No Additional Therapy for Patients Under Age 61 with Previously Untreated De Novo Acute Myeloid Leukemia. The Committee carefully reviewed detailed information about the potential toxic deaths that have occurred on both induction arms of the trial. The DSMC recommends that the study continue as planned. They also requested that if the next interim analysis of response for the induction arms could be conducted prior to the next scheduled DMSC meeting, the Committee would very much like to see those results when they become available. The DSMC also requested that other secondary endpoints such as progression-free survival and overall survival be provided at that time.

8. External Information
   S9917 – L-Selenium-Based Chemoprevention of Prostate Cancer Among Men with High Grade Prostatic Intraepithelial Neoplasia. Based on the recent press release of the results of SELECT (Selenium and Vitamin E Prevention Trial), the DSMC felt that for the 50 or so men who are still taking study supplements, they should be re-consented. The updated consent should indicate that although the SELECT population is different than that of S9917, the SELECT trial found convincing evidence that selenium in the same formulation and dose as S9917 did not prevent prostate cancer. Additionally, there was a small suggestion of an increased risk of diabetes on the selenium alone arm of SELECT (which was not statistically significant), but no increased risk was seen on the combination selenium + vitamin E arm. A good faith effort should be made to inform those men who have completed S9917 of the selenium-related results of SELECT.

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

Breast
S0221
S0226
S0307
S0500

Cancer Control
S0230

Gastrointestinal
S0502
S0518
S0600
S0727

Genitourinary
S9346
S0421
S0717

Leukemia
S0325

Lymphoma
S0410

Melanoma
S0008

The next DSMC meeting will be held as a conference call prior to the SWOG Group Meeting scheduled for April 22-25, 2009. Details will be arranged at a later date.

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