Southwest
Oncology Group
A National Clinical Research Group

November 1, 2007

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)

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 4, 2007 meeting is attached. The information from these reports 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.
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

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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: Dr. Baker , Dr. Crowley and Data and Safety Monitoring Committee: Drs. Piantadosi, Kempin, Korn, Langer, Macdonald, Martin, Minasian, Petrylak, Gaspar and Ms. Gottlieb

FROM: Cathy Tangen, DrPH

DATE: October 11, 2007

RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting of Thursday, October 4, 2007

1. Accrual

Cancer Control S0230 – A Phase III Trial of LHRH Analog Administration During Chemotherapy to Reduce Ovarian Failure Following Chemotherapy in Early Stage, Hormone-Receptor Negative Breast Cancer. This study had been slow accruing. However, with the addition of the IBCSG accrual has significantly improved. The DSMC commends the study leadership for improving accrual. No further action is needed at this time.

Cancer Control S0300 – A Randomized Placebo-Controlled Biomarker Modulation Trial Using Celecoxib in Pre-menopausal Women at High Risk for Breast Cancer. This study has had very slow accrual since its reactivation on December 15, 2005. An amendment was approved by DCP and mailed to participating sites on September 1, 2007 which increased the scope of eligibility to this study. It is expected this will increase accrual. The DSMC wants to see a total of 20 patients registered to this study by the next meeting in May, 2008, or else the Committee will recommend closure.

2. Data Request

Lymphoma S0016 – A Phase III Randomized Trial of CHOP Chemotherapy Plus Rituximab versus CHOP Chemotherapy Plus Iodine-131 Tositumomab for the Treatment of Newly Diagnosed Follicular Non-Hodgkin's Lymphoma. For disease committee planning purposes, Drs. Fisher and Press requested to see the progression-free survival curves by treatment arm. Based on the rationale that was presented by Dr. Fisher and the fact that the study will be closed to accrual in six months, the DSMC has given permission for these two investigators to have confidential access to this information for planning purposes.

3. Interim Feasibility Analysis

   GU S0437 – PCPT Companion Long Term Follow Up Study for Men Diagnosed with Prostate Cancer. Although the accrual feasibility endpoint has not been met, the DSMC voted that the study should continue and will be re-evaluated in six months time.

4. Adverse Events

   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. Because of a concern for a potential imbalance in the number of toxic deaths between the induction treatment arms, and the notable lack of toxic deaths on the standard arm, additional details about each toxic death were reviewed by the DSMC. The recommendation is that the study should continue. The statistician has been asked to provide race information for each patient who experienced a toxic death, and there was a request for a projection when the first interim analysis will be conducted with respect to response in the induction arm. If the interim analysis may be available before the next scheduled DSMC meeting, the committee will review the interim analysis results in an ad hoc teleconference as soon as the statisticians have prepared the interim analysis.

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

   Breast
   S0221
   S0226
   S0307
   S0500

   Gastrointestinal
   S0600

   Genitourinary
   S9346
   S9917
   S9921
   S0337
   S0421

   Leukemia
   S0325
   S0521

   Lung
   S0124

Lymphoma
S9704
S0410

Melanoma
S0008

Myeloma
S0232

The next meeting is scheduled for Thursday, May 1, 2008 at 5 pm at The Hyatt Regency in Atlanta, Georgia.