SWOG
Leading cancer research. Together.

GROUP CHAIR'S OFFICE
Charles D. Blanke, MD
CHAIR
3181 SW Sam Jackson Pk Rd
MC: L586
Portland, OR 97239
503-494-5586
503-346-8038 FAX

OPERATIONS OFFICE
4201 Medical Dr
Suite 250
San Antonio, TX 78229
210-614-8808
210-614-0006 FAX

STATISTICAL CENTER
1730 Minor Ave
Suite 1900
Seattle, WA 98101
206-652-2267
206-342-1616 FAX

1100 Fairview Ave North
M3-C102
PO Box 19024
Seattle, WA 98109
206-667-4623
206-667-4408 FAX

swog.org

June 1, 2013

TO: ALL SWOG MEMBER, CCOP, UCOP AND AFFILIATE MEDICAL ONCOLOGISTS, SURGEONS, RADIATION ONCOLOGISTS, PATHOLOGISTS AND CLINICAL RESEARCH ASSOCIATES; AND CTSU

FROM: Charles D. Blanke, M.D. - Chair

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 SWOG 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 SWOG 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 May 3, 2013 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).

This memorandum serves to notify the NCI and SWOG Statistical Center.

PC/dbs

Enclosure

cc: Cathy M. Tangen, Dr.P.H.
Nathan Erickson
Elaine Armstrong, M.S.
Dana B. Sparks, M.A.T.
Kati M. Stoermer, M.S.B.A.

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. Blanke, Dr. LeBlanc and Data and Safety Monitoring Committee

FROM: Cathy Tangen, DrPH

DATE: May 6, 2013

RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting of Friday, May 3, 2013

Interim Analysis

1. **GU S0337** – A Phase III Trial of Immediate Post-TURBT Instillation of Gemcitabine Versus Saline in Patients with Newly Diagnosed or Occasionally Recurring Grade I/II Superficial Bladder Cancer. The DSMC reviewed the planned first interim analysis. As no statistical boundary has been crossed, the Committee recommends the trial continue as planned. The study leadership may see confidential outcome data by treatment arm for the purposes of trial planning. These investigators should sign a confidentiality agreement in advance.

2. **GU S0925** – A Randomized Phase II Trial of Combined Androgen Deprivation with IMC-A12 versus Combined Androgen Deprivation for Patients with New Hormone-Sensitive Metastatic Prostate Cancer. The DSMC reviewed the planned interim analysis. No statistical boundary has been crossed, and so the recommendation is that the study should continue as planned.

3. **GI S0518** – A phase III prospective randomized comparison of depot octreotide plus interferon alpha versus depot octreotide plus bevacizumab in advanced, poor prognosis carcinoid patients. The DSMC evaluated the interim analysis and since no statistical boundary has been crossed, recommends the trial continue as planned. For the fall 2013 meeting, the DSMC would like to see a report of the level of agreement between the local site's calling of progression and ACRIN's calling of progression based on their blinded review of the same scans.

4. **Lung S0819** – A Randomized Phase III Study Comparing Carboplatin, Paclitaxel, Bevacizumab with or without Concurrent Cetuximab in Patients with Advanced Non-Small Cell Lung Cancer. The DSMC reviewed the interim analysis, and recommends the trial continue as planned. At the next planned interim analysis in spring 2014, the DSMC would like to see the analysis for the overall group, the EGFR FISH positive group, and the EGFR FISH negative group in that report.

5. **Myeloma S0777** – A Randomized Phase III Trial of Lenalidomide and Low Dose Dexamethasone versus Bortezomib, Lenalidomide and Low Dose Dexamethasone Induction in Patients with Previously Untreated Multiple Myeloma without an Intent for Immediate Autologous Stem Cell Transplant. The DSMC reviewed the interim analysis and recommends that the trial continue as planned.

   Other

6. **GU S0931** - A EVEREST: EVErolimus for Renal Cancer Ensuing Surgical Therapy: A Phase III Study. The DSMC encourages the S0931 study leadership to provide education to treating investigators regarding the management of side effects frequently seen by those patients taking everolimus. This should include the distribution of the Novartis drug pamphlet to sites enrolling patients.

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

Breast
S0307, S0500, S0800, S1007

Cancer Control
S0812, S0820, S0927, S1105, S1200

Gastrointestinal
S1115, S1201

Genitourinary
S1011, S1216

Leukemia
S1117, S1203

Lung
S0905

The next DSMC meeting is tentatively expected to be held in-person on Friday, October 11, 2013 in Chicago, IL. Details still to be confirmed.