SWOG
Leading cancer research. Together.

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October 15, 2016

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 September 16, 2016 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.

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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: September 20, 2016
RE: SWOG DSMC – Final minutes of SWOG Data and Safety Monitoring Committee Meeting of Friday, September 16, 2016

1. Prevention S0820 – *Preventing Adenomas of the Colon with Eflornithine and Sulindac (PACES).* The DSMC remains concerned about the feasibility of accrual to this study. S0820 study leadership informed the DSMC that they plan to redesign the trial with a lower sample size and submit to DCP for their review. The DSMC would like to be informed of the status of those discussions by the time of our next meeting.

2. **Gastrointestinal S1313**: *A Phase I/II Randomized Study of Modified Folfirinox + Pegylated Recombinant Human Hyaluronidase (PEGPH20) Versus Modified Folfirinox Alone in Patients with Good Performance Status Metastatic Pancreatic Adenocarcinoma.* The DSMC has carefully reviewed the safety data for this trial, and we recommend the study continue as planned. However, the DSMC requests an additional safety interim analysis by Dec. 1, 2016 in a format similar to what was presented in mid-May, 2016. The DSMC would like to see the AE data stratified by whether prophylactic warfarin was received. The Committee would also like to know the proportion of patients who were randomized to the experimental arm after the Feb. 2016 memo about supportive care, and received warfarin.

3. Breast S1207: *Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer*. The DSMC encourages the study leadership to continue to be proactive about educating and supporting symptom management in order to minimize the number of patients going off protocol treatment prematurely. The DSMC understands that a study design amendment is planned to be submitted to CTEP. The Committee requests an update on that amendment for the spring 2017 meeting.

4. Melanoma S1320: *A Randomized Phase II Trial of Intermittent versus Continuous Dosing of Dabrafenib and Trametinib in BRAF Mutant Melanoma.* The study team's request to assess associations between known and hypothesized markers of resistance and response based on the first disease assessment at 8 weeks (prior to randomization) has been approved by the

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DSMC. However, any plans for public reporting of these results must receive prior approval by the DSMC, and should not occur until after accrual has been completed.

5. **CC S1316:** *Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction.* The DSMC expressed concern about the lack of patient randomizations on this study, and that among those in the cohort the majority are choosing non-surgical intervention. The DSMC will evaluate the number of randomizations at our next meeting, after Latin American sites have started enrollment. If randomization appears to be infeasible, the study objectives will need to be re-evaluated to reflect what can be addressed in a non-randomized trial.

6. **Lung S1400 and its substudies**: *A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer (Lung-MAP)*. The current status of the screening step and substudies was discussed. There were no recommendations or concerns.

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

Breast: S1007

Cancer Control: S1105, S1200

Gastrointestinal: S1505

Genitourinary: S0931, S1011, S1216, S1314, S1500

Leukemia: S1318

Lung: S1206, S1300, S1403

Melanoma: S1404

Myeloma: S1211, S1304

The next DSMC meeting is expected to be held by phone (in person for those attending to the spring SWOG Group meeting), tentatively on Friday, April 28, 2017 at 7:30 am PT, coinciding with the SWOG Group Meeting in San Francisco. Details will be confirmed later.