SWOG
Leading cancer research. Together.

MEMORANDUM

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

DATE: June 15, 2013

TO: SWOG Principal Investigators, Pharmacists, and Clinical Research Associates

FROM: SWOG Quality Assurance Department

SUBJECT: Updates to SWOG Audit Procedures

The updated CTMB/NCI *Guidelines for Auditing of Clinical Trials for Cooperative Groups, CCOP Research Bases, and the Cancer Trials Support Unit (CTSU),* effective January 1, 2013, included changes that will affect how SWOG conducts audits.

Regulatory review

The previous version of the guidelines stated external safety reports must be submitted to the local IRB within 90 days of distribution ***unless the institution's local policy outlined alternate procedures***. The updated 2012 guidelines state that ***unanticipated problems as defined by OHRP policy including external safety reports*** must be reported to the IRB within 90 days of distribution.

While many of the external safety reports distributed by the cooperative groups do not meet the definition of "unanticipated problems", your local policy must at a minimum adhere to the policy set by OHRP which requires unanticipated problems to be reported to your IRB. A random sample of at least 10% of external safety reports reportable per OHRP policy will be verified for each protocol selected for audit.

Pharmacy operations and IND accountability

The review of pharmacy operations will now require the auditor to verify that written procedures are in place at the site/pharmacy to ensure that the physician ordering NCI supplied-agents is an investigator registered with the Pharmaceutical Management Branch (PMB) or that the order/prescription is co-signed by a registered investigator.

The updated guidelines require that the investigator ordering investigational agents is registered with PMB. These procedures are meant to ensure compliance with Section 14.2 of the *Handbook for Clinical Investigators Conducting Therapeutic Clinical Trials Supported by CTEP, DCTD, NCI* which states that "Patient-specific orders for [NCI-supplied] study agents should be written by NCI-registered investigators participating on the specific trial. If other licensed prescribers write orders, the registered investigator who is officially participating on the trial must co-sign the order." (See http://ctep.cancer.gov/investigatorResources/docs/InvestigatorHandbook.pdf.)

Specific procedures are at the discretion of the institution, investigator, or pharmacy, however procedures may include:

- Maintaining a log of NCI-registered investigators to be referenced prior to filling any order of NCI-supplied agent.

- Accessing http://ctep.cancer.gov/branches/pmb/expiration_date.htm prior to filling an order. This will require the pharmacist to enter the last name and investigator ID number.

While the following are not new, sites are reminded of the following requirements that often are seen as non-compliant during audits:

- CTEP supplied investigational agents may not be repackaged and/or reshipped to other investigators, patients or locations by mail or express carrier. Note: With prior approval from SWOG, permission to ship investigational agents that are not supplied by CTEP directly to a patient may be allowed on a case by case basis.

- Investigational agents that are expired or are no longer usable (e.g. all patients are off treatment on a closed study, patient on blinded study is off treatment) must be destroyed or returned within 90 days of end of use. Agents from closed studies may be transferred to another active NCI protocol.

Compliance to the new audit procedures will be required effective August 15, 2013. If you have questions, please contact Elaine Armstrong at earmstrong@swog.org.