Southwest
Oncology Group
A National Clinical Research Group

January 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: SWOG Operations Office

RE: Changes in SWOG SAE Reporting Processes

MEMORANDUM

Effective this date, Southwest Oncology Group's requirements regarding submission of supporting documentation when reporting serious adverse events (SAEs) is changed as outlined below, implementing the changes in SWOG Policy 23, "Serious Adverse Events."

PLEASE NOTE: The guidelines for what events must be reported on an expedited basis have **not** changed. The SAE reporting guidelines themselves in Section 16 of SWOG protocols must be followed as written. The changes in SWOG Policy 23 and this memo apply **only** to supporting documentation requirements.

In general, the supporting documentation requirements for SWOG SAE reports now depend on whether (1) the patient has received investigational (IND) drug, and (2) if so, what entity holds the IND for that drug. These requirements are shown in the table on the next page.

You will note that in every case it is no longer a requirement to submit evidence to SWOG that the IRB was notified of a reported SAE. The necessity of notifying IRBs of all serious adverse events has not changed, however, and documentation of that notification must be available for review during audits.

New SWOG protocols will contain the appropriate supporting documentation submission instructions upon activation, and these instructions will be added to presently open studies whenever they are amended for other purposes. However, these new instructions should be implemented immediately, even if a protocol has not yet been amended to include them. This memo serves as the authorization to do this. As a convenient reference until these protocol changes can be made, the list on pages 3 and 4 shows which of the above three categories the open and recently closed SWOG studies are in.

Especially during the transition period until protocols can be fully amended and the new routine becomes established, please do not hesitate to contact the Serious Adverse Events Manager at the Operations Office with any questions about supporting documentation: telephone 210-450-8808 or email adr@swog.org.

For a SWOG patient who has received:	**After submitting the initial report of the SAE, send to the SWOG Operations Office:**
An investigational drug on a study for which SWOG holds the IND	Within 5 or 10 calendar days*: o A copy of the SAE report o Clinical documentation substantiating the reported event; in most cases, a discharge summary for hospitalizations or equivalent outpatient clinical data *As specified in Section 16 of the protocol
An investigational drug on a study for which NCI holds the IND	Clinical documentation substantiating the reported event only upon request by SWOG Operations. Clinical documentation should be submitted to NCI if previously indicated in an AdEERS report, but this documentation need not be submitted to SWOG Ops unless specifically requested.
Only commercial drugs	Clinical documentation substantiating the reported event only upon request by SWOG Operations.

QAA/nm

IND STATUS OF SOUTHWEST ONCOLOGY GROUP PROTOCOLS*				
Protocol No.	IND Holder			Rmks
	NCI	SWOG	None (Commercial drug)	
SWOG-9346			C	
S9704			C	
S9917		S		
S9921			C	
S0008			C	Reporting requirements depend on arm or step
S0009			C	
S0016		S	C	Reporting requirements depend on arm or step
S0106		S	C	Reporting requirements depend on arm or step
S0115			C	
S0124		S	C	Reporting requirements depend on arm or step
S0204			C	
S0220			C	
S0221			C	
S0226		S	C	Reporting requirements depend on arm or step
S0230			C	
S0300			C	
S0301			C	
S0307		S	C	Reporting requirements depend on arm or step
S0313			C	
S0325	N		C	Reporting requirements depend on arm or step
S0329			C	
S0333			C	
S0337		S		
S0350			C	
S0353			C	
S0354		S		
S0356			C	
S0410			C	
S0412	N			
S0414			C	
S0415			C	
S0417			C	
S0421		S		
S0425			C	
S0429			C	
S0430			C	
S0432	N			
S0433			C	
S0434	N			
S0435	N			
S0438	N			
S0500			C	
S0505	N			
S0509	N			
S0512	N		C	Reporting requirements depend on arm or step
S0514	N			
S0515	N			
S0517	N			

IND STATUS OF SOUTHWEST ONCOLOGY GROUP PROTOCOLS (Cont'd)*				
Protocol No.	IND Holder			Rmks
	NCI	SWOG	None (Commercial drug)	
S0518	N		C	Reporting requirements depend on arm or step
S0520	N			
S0521			C	
S0526			C	
S0528		S		
S0530			C	
S0533	N		C	Reporting requirements depend on arm or step
S0535			C	
S0536	N			
S0600	N		C	Reporting requirements depend on arm or step
S0601			C	
S0605	N			
S0618	N			
S0622		S		
S0635		S		
S0636		S		

*If a reportable event occurs on a study that is not listed, contact the Operations Office SAE Program at 210-450-8808 or email adr@swog.org.