Southwest
Oncology Group
A National Clinical Research Group

MEMORANDUM

TO: ALL SOUTHWEST ONCOLOGY GROUP MEMBER, CCOP AND AFFILIATE INVESTIGATORS AND CRAs

FROM: Nickey McCasland, RN
SAE Program Manager

DATE: August 15, 2004

SUBJECT: Serious Adverse Event Reporting in Southwest Oncology Group

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Version 5.0 of NCI's AdEERS (Adverse Event Expedited Reporting System), released June 1, 2004, expands its capability for expedited reporting of serious adverse events (SAEs). SAEs on all types of treatment studies, i.e., those using commercial drugs, investigational drugs, a combination of commercial and investigational drugs, surgery, or radiation therapy, will now be reported in AdEERS. The MedWatch form will be phased out for SAE reporting on SWOG protocols. Open protocols are being revised to this effect starting with the July 15 mailing; these revisions will also implement a new intergroup standard format for SAE guidelines. Only the formatting of the guidelines has changed, not the guidelines themselves.

The only exceptions to AdEERS reporting will be

- Intergroup protocols that specify another method of SAE reporting
- Preventive studies such as **S0000** (SELECT)
- Reporting of AML/MDS in patients previously treated on an NCI protocol (AML/MDS reporting will be added to AdEERS later, but in the meantime the AML/MDS form will continue to be used.)

A few key points about the new reporting procedures:

- The Operations Office must still be notified of SAEs within 24 hours. Telephone notification is preferred, as always. However, in cases where no assistance is needed with the report and its necessity is clear according to protocol guidelines, submitting the *complete* AdEERS report within 24 hours will suffice as this notification.

- Please note that the "AdEERS Report with 24-Hour Notification" Option is only for use when specified in the protocol (usually only for grade 4 or 5 unexpected adverse events under investigational drug guidelines), and when used, the complete report must still be submitted within seven working days.

- Use only those optional AdEERS sections that are relevant to the event being reported. If any optional sections are not needed, such as Pre-Existing Conditions or Concomitant Medications, for example, they should be switched to "No" on the Sections of Report page.

- The new SAE reporting guidelines require supporting documentation to be submitted to the Operations Office within seven working days rather than ten, but it will no longer be necessary to submit a standard dataset (prestudy forms, all treatment and adverse event forms) with all reports. Only the clinical data relevant to the SAE being reported need be submitted, along with a copy of the AdEERS report and a copy of the IRB notification document. Questions about what supporting data is required should be directed to the SAE Program in the Operations Office.

- In the AdEERS Additional Information section, "Summary Report Sent to IRB" should always be checked; other items should be checked as applicable to the event being reported.

Should you have any questions about this changes in procedures, please contact the Operations Office at 210/677-8808.