COMPREHENSIVE CANCER CENTER
MICHIGAN MEDICINE

Multi-Site Protocol Template Language

Serious Adverse Event Reporting

All serious adverse events (SAEs) and unanticipated problems (UPs), regardless of causality to study drug, will be reported to the Principal Investigator and also to the Coordinating Center. All SAEs and UPs must be reported to the Coordinating Center within 24 hours of first awareness of the event. Events should be reported using the **[Insert MedWatch 3500A form OR Coordinating Center SAE form as available in the study database** ***contact the Multi-Site team Manager to discuss which form is most appropriate for your study*]. A copy of the **[Insert MedWatch 3500A form OR Coordinating Center SAE form as available in the study database]** should be sent to the Coordinating Center via fax at 734-232-0744 or via email to CTO-Multisite@med.umich.edu within 24 hours of the site's knowledge of the event.

Contact information for Principal Investigator SAE Reporting:

Name
Address
Telephone:
Fax:
Email:

Follow-up information must also be reported within 24 hours of receipt of the information by the investigator.

All SAEs and UPs will be reported to the IRB per current institutional standards.

The Coordinating Center will disseminate information regarding SAEs and UPs to the participating sites within 5 days of review of the information by the Coordinating Center's Principal Investigator (or designee in the event of extended absence) only in the case that the event(s) is believed to be related (i.e., possibly, probably, or definitely) to the study drug. The Coordinating Center will be responsible for reporting of events to the **[FDA and supporters]**, as appropriate (outlined below).

The Coordinating Center will be responsible for reporting to [**Insert Supporter**] by [**insert method: fax or email**] any SAEs and UPs that occur during the reporting period [**insert contract language regarding safety reporting**].

In this trial, serious unexpected adverse events believed to be definitely, probably or possibly related to the study treatment will be reported to the Food and Drug Administration via the MedWatch 3500A. The Coordinating Center will be responsible for correspondence regarding adverse events with the FDA for all participating sites.