

Initial Report Complete and fax to CERU at 613-548-2428 attention: Project Leader REDOXS **within 48 hrs of becoming aware of event.**

Complete one form for EVERY adverse event that is ***Serious and Unexpected***. Report only those SAEs that occur from the time of randomization to the end of the study period (30 days from admission to ICU or until ICU d/c or death, whatever occurs first).

<p>Patient Identification</p> <p>Site # _____</p> <p>Enrollment # _____</p> <p>Initials _____</p> <p>DOB _____ / _____ / _____</p> <p style="padding-left: 40px;">dd mmm yr</p> <p><input type="checkbox"/> Male <input type="checkbox"/> Female</p>	<p>Name of Site Investigator</p> <p>Person reporting SAE</p>	<p>SAE # _____</p> <p>Record the sequential SAE # for this patient i.e. For 1st SAE for this patient, write 01 For 2nd SAE for this patient, write 02</p>	<p>Date SAE reported</p> <p>_____ / _____ / _____</p> <p style="padding-left: 40px;">dd mmm yr</p> <hr/> <p>Date became aware of SAE</p> <p>_____ / _____ / _____</p> <p style="padding-left: 40px;">dd mmm yr</p>
<p>Serious Adverse Event Reported (only one per form)</p>			
<p>Seriousness (select all that apply)</p> <p><input type="checkbox"/> Patient died → please document date in Outcomes</p> <p><input type="checkbox"/> Life threatening</p> <p><input type="checkbox"/> Requires or prolongs hospitalization</p> <p><input type="checkbox"/> Results in persistent or significant disability/incapacity</p> <p><input type="checkbox"/> May require medical or surgical intervention to prevent one of the other outcomes to defining serious</p>		<p>Outcomes (at time of initial report)</p> <p><input type="checkbox"/> Complete recovery/return to baseline → Date of recovery dd ___ / mmm ___ / yr ___</p> <p><input type="checkbox"/> Alive with sequelae</p> <p><input type="checkbox"/> Death → death date dd ___ / mmm ___ / yr ___</p> <p><input type="checkbox"/> SAE persisting</p> <p><input type="checkbox"/> Unknown/lost to follow-up</p>	
<p>Onset of SAE</p> <p>_____ / _____ / _____</p> <p style="padding-left: 40px;">dd mmm yr</p>	<p>Admission to ICU</p> <p>_____ / _____ / _____</p> <p style="padding-left: 40px;">dd mmm yr</p>	<p>Start of Study Supplements</p> <p>_____ / _____ / _____</p> <p style="padding-left: 40px;">dd mmm yr</p>	<p>Resolution of SAE</p> <p>_____ / _____ / _____</p> <p style="padding-left: 40px;">dd mmm yr</p>
<p>Action Taken</p> <p><input type="checkbox"/> None</p> <p><input type="checkbox"/> Uncertain</p> <p><input type="checkbox"/> Procedure or physical therapy</p> <p><input type="checkbox"/> Blood or blood products</p> <p><input type="checkbox"/> Prescription drug therapy</p> <p><input type="checkbox"/> Non-prescription drug therapy</p> <p><input type="checkbox"/> Hospitalization</p> <p><input type="checkbox"/> IV fluids</p> <p><input type="checkbox"/> Other , specify _____</p>	<p>Action taken with Study Supplements</p> <p><input type="checkbox"/> None (including not on study supplements)</p> <p><input type="checkbox"/> Dose reduced, interrupted or therapy delayed</p> <p><input type="checkbox"/> Study supplements stopped permanently due to SAE</p>	<p>Relationship of SAE to Study Supplements</p> <p><input type="checkbox"/> Not related</p> <p><input type="checkbox"/> Unlikely related</p> <p><input type="checkbox"/> Possibly related</p> <p><input type="checkbox"/> Probably related</p>	<p>Signature of Principal Investigator</p> <p>_____</p> <p>Date</p> <p>_____ / _____ / _____</p> <p style="padding-left: 40px;">dd mmm yr</p>

Follow up with a Final Report (on page 2) within specified timelines.