

UWO – HSREB	INSTRUCTIONS	2-I-003	Page 1 of 2
Effective date: June 1, 2004 Revised December 6, 2005 February 4, 2009 April 15, 2009	REPORTING OF ADVERSE REACTIONS & EVENTS		

REPORTING REQUIREMENTS	
<p>The Office of Research Ethics is in the process of converting from hard copy submissions to an online system. Eventually all Adverse Event reporting forms will be online.</p> <p>Investigators are strongly encouraged to use the online reporting options when available. https://grant2.vm.its.uwo.ca/sae/SAELogin.aspx</p> <p>Investigators submitting Adverse Events online can receive a confirmation that the Adverse Events were electronically submitted by using the “Search & Print” function.</p> <p>All hard copy submissions and documents should be sent to: THE OFFICE OF RESEARCH ETHICS ~ ROOM 4180 Support Services Building UWO</p>	
LOCAL SITES	<p>SERIOUS, UNEXPECTED adverse events or reactions REGARDLESS OF CAUSALITY for subjects enrolled at the Local site.</p> <p>Within 7 days of discovery of the event or reaction submit 1 hard copy of UWO HSREB <u>Local Adverse Events Report</u> that is generated through the On-Line Adverse Events Reporting system. Please ensure that YOU ALSO forward a hard copy of the event within 7 days (i.e. print copy for your records, sign and submit) at: https://grant2.vm.its.uwo.ca/sae/SAELogin.aspx</p>
NON-LOCAL SITES	<p>SERIOUS, UNEXPECTED adverse reactions or events RELATED TO THE STUDY INTERVENTION that occur at all non-local or external sites</p> <p>Within 30 days of being notified of the event or reaction submit:</p> <ul style="list-style-type: none"> An online <u>Non-Local Adverse Events Report</u> https://grant2.vm.its.uwo.ca/sae/SAELogin.aspx <p>Hard copies are no longer accepted.</p>
OTHER TRIALS & SPONTANEOUS REPORTING	<p>Within 30 days of being notified of the event or reaction submit:</p> <ul style="list-style-type: none"> An online <u>Other Studies or Spontaneous Adverse Events Report</u> https://grant2.vm.its.uwo.ca/sae/SAELogin.aspx <p>Hard copies are no longer accepted.</p>
Summary (Safety) Reports	<p>A succinct summary from a Data Safety Monitoring Committee or comparable group that assesses the implications of the Adverse Events from the other clinical studies or spontaneous reporting and relates them specifically to the protocol approved by the UWO REB</p> <p>Please use the DSMC/DSMB form available at: http://www.uwo.ca/research/ethics/new_forms_dec08.html</p>
<p>Investigators may submit other reporting forms or documentation as required by sponsors and regulatory authorities. These reports and documents must be accompanied by either a printed version of the online AE report or the usual hard copy form.</p> <p>Sponsor summaries may be submitted in lieu of the Non-Local and Other Studies Reporting forms but only if prior approval has been received from the Office of Research Ethics</p>	

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DEFINITIONS: <i>An adverse event or reaction is considered to be:</i>	
SERIOUS	As defined in: <ul style="list-style-type: none"> • ICH Guideline: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting E2A Section II B or • Canada's Food & Drug Regulations (1024 – Clinical Trials) Division 5 C.05.001
UNEXPECTED	<ul style="list-style-type: none"> • If it is not identified in nature, severity or frequency in regulatory documents such as the Investigator's Brochure or Product Monograph; or in the REB approved research protocol or informed consent document.
RELATED TO THE RESEARCH INTERVENTION	<ul style="list-style-type: none"> • If there is a reasonable possibility that the reaction or event may have been caused by the research intervention (i.e. a causal relationship between the reaction and the research intervention cannot be ruled out by the investigator(s)).