

UWO – HSREB	GUIDELINE	2-G-015	Page 1 of 1
Effective date: February 1, 2003 Revised 04/06/01 Revised 2009/09/30	REPORTING PROTOCOL VIOLATIONS, DEVIATIONS & WAIVERS		

REB RESPONSE: The REB will not give retroactive approval of violations that are reported after the fact; nor will it acknowledge receipt of notification of those violations.	
REPORTING FORMAT: Protocol violations must be reported on the appropriate UWO form as noted below.	
DEFINITIONS:	
Protocol Violation <i>General term</i>	This is a term broadly used in clinical research to describe any study event whereby the current REB-approved research protocol was not followed, i.e. a change in a research activity. There is general acceptance in the biopharmaceutical industry for two categories of protocol violation, i.e. a protocol deviation and a protocol exception.
Protocol Deviation: <i>General</i> <i>Discovered after occurrence. Post event report to REB.</i> <i>N.B. The only acceptable protocol deviation is when urgent action is required to eliminate an immediate hazard to a subject.</i>	An unanticipated or unintentional divergence or departure from the expected conduct of an approved study that is not consistent with the current research protocol, consent document or study addenda. <i>Protocol Deviations must be reported to the REB within 7 days of their discovery by using the HSREB Protocol Deviation Report. A copy of the sponsor protocol violation, deviation or waiver form should be appended to the UWO form. Other supporting documentation should be retained by the Investigator and be made available upon request.</i> Exclusion: <i>Minor</i> protocol deviations do not have to be reported to the REB. A minor protocol deviation does not affect the overall evaluability of the participant for either efficacy or safety. Examples of minor protocol deviations include out-of-window procedures or visits or non-essential lab tests that were not performed. Minor protocol deviations do not include recurring deviations that could affect the conduct of the study or deviations that could adversely affect participant safety or wellbeing.
Protocol Deviation: <i>Inclusion / Exclusion Waivers</i> <i>Post event notification acceptable for minimal risk waivers only.</i>	These are <u>single occurrence</u> deviations in inclusion/exclusion criteria. In general they are a planned exception that should receive REB approval before being implemented. However the REB recognizes that in some cases time may be of the essence in enrolling participants. Therefore, enrollment waivers, that in the opinion of the local Principal Investigator, are minimal risk i.e. have no potential for negative impact on the health and safety of the research participant may be implemented without prior REB approval. All others should be sent to the REB for prior approval. <i>Protocol Deviations must be reported to the REB within 7 days of implementation by using the HSREB Protocol Deviation Report. A copy of the sponsor protocol violation, deviation or waiver form should be appended to the UWO form. Other supporting documentation should be retained by the Investigator and be made available upon request.</i>
Protocol Exception (Revision &/or Amendment) <i>Planned exception requiring prior REB approval.</i>	A divergence or departure from expected conduct of an approved study that is not consistent with the current research protocol, consent document or addenda that had been anticipated by the investigator, and for which REB grants acceptance. <i>Requests for a Protocol Exception (or Revision) should be made to the REB by using the HSREB Request for a Revision form prior to the implementation of the change.</i>