

RESEARCH ETHICS BOARD
**INSTRUCTIONS FOR REPORTING PROTOCOL DEVIATIONS,
VIOLATIONS AND WAIVERS**

Acknowledgement: We would like to thank Hamilton Health Sciences, St. Joseph's Healthcare Hamilton and McMaster University for their permission to use this document and modify it to suit the needs of St. Joseph's Health Centre

REPORTING FORMAT: Protocol violations must be reported on the appropriate form as noted below.	
DEFINITIONS:	
Protocol Violation General term	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: General Term Discovered after occurrence. Post event report to REB. N.B. The only acceptable protocol deviation is when urgent action is required to eliminate an immediate hazard to a subject.	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. Protocol Deviations must be reported to the REB within 7 days of their discovery using SJHC Protocol Deviation Report attached. If applicable, a copy of the sponsor protocol violation, deviation or waiver form should be appended to the form. Other supporting documentation should be retained by the Investigator and be made available upon request.
Protocol Exception: Inclusion / Exclusion Waivers Post event notification acceptable for minimal risk waivers only.	These are single occurrence 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 using the Amendment Request Form. Protocol Exceptions must be reported to the REB within 7 days of implementation if the deviation affects patient safety or the integrity/outcome of the study. All others must be reported within a timely fashion, e.g., no greater than 2 months from the time of occurrence using the Protocol Deviation Report. A copy of the sponsor protocol violation, deviation or waiver form should be appended to the SJHC Protocol Deviation Report form attached. Other supporting documentation should be retained by the Investigator and be made available upon request.
Do not use the attached Protocol Deviation Report for requests for approval of <u>planned or future exceptions or revisions</u> (i.e. a protocol change that is more than a single occurrence deviation). 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 <u>must be submitted to the REB for amendment approval.</u>	

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PROTOCOL DEVIATIONS, VIOLATIONS AND WAIVERS REPORT

This form is available in MS WORD & PDF formats and can be downloaded at: <http://www.stjoe.on.ca/education/research.php>

Principal Investigator:			
SJHC Local Study Lead (if different from above):			
REB Study #		Study Title:	
What kind of Protocol Deviation is being reported? (See Guidelines – Reporting Protocol Violations, Deviations & Waivers for definitions)			General <input type="checkbox"/>
			Inclusion/Exclusion Waiver <input type="checkbox"/>

Study Contact for REB Response Letter (Name, Institution, Mailing address, Telephone #, Email)
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1a	Please provide a brief synopsis of the protocol deviation	
1b	Date(s) when the protocol deviation occurred	

2a	In the opinion of the On-Site Lead, does this deviation compromise the scientific integrity of the study?	YES	<input type="checkbox"/>
		NO	<input type="checkbox"/>
2b	If YES, describe how this deviation will compromise the scientific integrity of the study. If NO, please justify.		

3a	In the opinion of the On-Site Lead, did the deviation increase the risk or the possibility of risk for the research participant(s)?	YES	<input type="checkbox"/>
		NO	<input type="checkbox"/>
3b	If YES, discuss the increased risks. If NO, please justify.		

4a	Was the protocol deviation the result of an error or incorrect action by the sponsor, investigator(s) and/or his/her staff?	YES	<input type="checkbox"/>
		NO	<input type="checkbox"/>
4b	If YES, indicate what measures have been/will be taken to ensure this, or a similar problem, will not occur again.		

5a	Was the protocol deviation caused by the research participant?	YES	<input type="checkbox"/>
		NO	<input type="checkbox"/>
5b	If YES, indicate what measures have been/will be taken to ensure this, or a similar problem, will not occur again.		

6a	Have you attached a copy of the Sponsor's protocol violation, deviation or waiver form?	YES	<input type="checkbox"/>
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Attach a copy of the sponsor's protocol deviation reporting form to this report if available. Other supporting documentation should be retained by the Investigator and be made available upon request.	Not Applicable	<input type="checkbox"/>
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7a	Signature of Principal Investigator:	Date:
7b	Signature of Local Study Lead (if applicable):	Date:

Please submit this report and any supporting documents to the REB Coordinator at the address noted below. The original signature is required. If you have questions call 416-530-6486 X4193 or email santost@stjoe.on.ca.

Research Ethics Board Coordinator
 St. Joseph's Health Centre
 30 The Queensway, Room 7S712
 Toronto, ON, M6R 1B5

REB REVIEW *(This box to be completed by the Research Ethics Board Chair)*

- Further review is NOT required by the REB
- REB Response letter with questions about protocol deviation
- Changes are required by the REB

Recommendations:

- Protocol change:** YES NO
Consent Form change: YES NO
Description of Changes Required:

Final Decision by REB Chair/REB:

- To be determined
- Approved for continuation
- Approved conditional on changes
- Suspended pending further review

COMMENTS:

Signature of Chair, REB (or Designate)

Date