

REPORTING FORM – MINOR MODIFICATION

Please submit the **original and 1 copy** for REB review, including all revised documentation.

REB PROTOCOL NUMBER:		SPONSOR'S PROTOCOL NUMBER:		CHEO RI COST CENTRE:	
PROTOCOL TITLE:					
PRIMARY CHEO SITE INVESTIGATOR:			Telephone:		
			Email:		
CURRENT PROTOCOL VERSION CODE/DATE:					
Have any of the co-investigators been added or removed since the last approval? <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, please specify names below:					
SECONDARY CHEO CO-INVESTIGATORS <i>(use supplementary pages as required)</i>					
Name:	Division or PSU:	Telephone:	Email:		
Date of First Patient Enrolled locally:					
Number of potential subjects approached for study participation locally:					
Number of subjects (patients) recruited locally since last approval:					
Main Reason for withdrawals:					

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Has there been any departure from the approved protocol procedures (please describe below):

Inclusion/Exclusion Criteria Yes No

Source of subject (patient) population? Yes No

Other?

Please describe:

A copy of last approved Consent Form must be appended to this report.

Has the consent form been modified since last approval? Yes No

Has the REB been informed of these changes? Yes No If yes, indicate date approved: _____

Has any unexpected side effects, adverse events, or findings been noted since last approval? Yes No

Has the REB been informed of these? Yes No If yes, indicate date approved: _____

Have these SAEs been reviewed by the DSMB since last annual approval. If yes, please append the DSMB report to this submission. Any recommended protocol revisions made by the DSMB must be submitted separately for protocol amendments

Has any information appeared in the literature, or evolved from this or other similar ongoing studies (including interim analyses), since the date of last approval that might affect the perception of the risks and benefits of the study?

Yes No

If yes, provide this information and your assessment of it in the section on progress of the study). Has the REB been informed of these? Yes No If yes, indicated date submitted: _____

PLEASE ATTACH THE FOLLOWING:

- Revised documents with all changes appearing in bolded text (one copy).
- Revised documents printed on original letterhead (two copies required).

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IN THE SPACE BELOW, PLEASE PROVIDE A SHORT SUMMARY OF THE MODIFICATIONS BEING MADE AT THIS TIME. PLEASE TYPE OR PRINT CLEARLY.

[Empty space for providing a short summary of modifications]

Signature of Primary CHEO Site Investigator:	Date:
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Please forward to:
Ms. Natalie Morocz, Administrative Assistant
Research Ethics Board
Children's Hospital of Eastern Ontario
Room R249, 401 Smyth Road, Ottawa, Ontario, K1H 8L1
Telephone: (613) 737-7600, ext. 3350

CHEO Research Ethics Board - APPROVAL
Chair's Signature: _____
Date: _____