

REB Annual Renewal/Final Report Form

- The Tri-Council Policy Statement (TCPS) and Good Clinical Practice Guideline (GCP) require REB review of ongoing studies; this is achieved by the completion of an Annual Renewal Form. Closed studies require a Final Report Form. *Study closure* refers to the completion of recruitment and all follow-up components of a study at SJHC. Please note that, in some cases, specific external reporting requirements may require annual renewal even after a study has closed.
- Please type your response on the form. (Use the tab key to move between fields.)
- Investigators are reminded that all changes to the approved protocol and consent documents, as well as any serious adverse events, must be submitted for REB review. *Revised procedures, consent forms, etc. are not to be used prior to approval.*
- A suspension of approval may occur if we do not receive the renewal form by the last day of the month proceeding the anniversary month.

**Please indicate: This is an Annual Renewal Form
This is a Final Report Form**

SJHC REB Study #:	
Study Title:	

Principal Investigator				
Title:	Principal Investigator:		Tel:	
Institution Name:		Dept/ Program:	Fax:	
			Pager:	
Mailing Address: (including room #)			Email:	

SJHC Local Study Lead (if there is an external PI)				
Title:	Name:	Tel:	Fax:	
Institution Name:		Pager:	Email:	
Department/Division:		Program:		
Mailing Address (including room #):				

Study Coordinator or Administrative Contact					N/A <input type="checkbox"/>	
Title:		Name:		Tel:		
Institution Name:						
Address:		Dept:		Fax:		
		Program:		Email:		
Please indicate to whom correspondence should be sent:					<input type="checkbox"/> PI	<input type="checkbox"/> Coordinator

Project Summary		
Original Approval Date:		
Previous Annual Renewal Approval Date:		<input type="checkbox"/> N/A
Study Abstract:		
Brief summary of the study progress and results to date:		
What is the funding status? Indicate the source and funding period.		
What is the version#/date of the Study Protocol or Study Amendment currently in use?		<input type="checkbox"/> N/A
What is the version #/date of the Informed Consent Form currently in use?		<input type="checkbox"/> N/A
Are Human Subjects being used?	<input type="checkbox"/> Yes Start Date (dd/mm/yy): End Date (mm/dd/yy):	<input type="checkbox"/> No
Secondary Analysis of Data Only (i.e. new research question/analysis using collected data):	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Has this study been subjected to audit this year?	<input type="checkbox"/> Yes By whom? How frequently? What were the audit results?	<input type="checkbox"/> No
Have there been any publications of this research?	<input type="checkbox"/> Yes Please attach a copy of the publication(s) to this form.	<input type="checkbox"/> No
Has there been any change in the Conflict of Interest information provided in the original REB application form (i.e. acting as an employee/consultant to the study sponsor, direct/indirect financial interest in the drug, device or technology involved in the study, receiving honorarium/benefits from the sponsor):	<input type="checkbox"/> Yes Please Describe:	<input type="checkbox"/> No

Enrollment Status		
What is your enrollment status? (Check all boxes that apply):	<input type="checkbox"/> No enrollment to date Reason:	
	<input type="checkbox"/> Enrolling subjects	
	<input type="checkbox"/> Enrollment complete but study is ongoing	
	<input type="checkbox"/> Post-treatment follow-up of subjects (i.e. follow-up visits, data collection only)	
	<input type="checkbox"/> Treatment and follow-up complete for all SJHC patients, but data clarification and/or data transfer ongoing (i.e. sponsors or coordinating centers)	
	<input type="checkbox"/> Premature termination of the study by investigator or sponsor. Reason for termination: Termination Date (dd/mm/yy):	
	<input type="checkbox"/> Study completed (i.e. no further subject involvement/data collection, clarification & transfer) Date Closed (dd/mm/yy):	
If subjects have been enrolled in the study:	Number of Subjects Originally Planned:	
	Number of Eligible Subjects Approached: N/A <input type="checkbox"/>	
	Number of Subjects Consented: N/A <input type="checkbox"/>	
	Number of Screen Failures (Post-Consent): N/A <input type="checkbox"/>	
	Number of Subjects Currently in the Study: N/A <input type="checkbox"/>	
	Number of Subjects that have Completed the Study: N/A <input type="checkbox"/>	
	How many subjects that have Completed and are Currently in the Study are: Male: Female:	
	Number of Subjects that Prematurely Withdrew from the Study: N/A <input type="checkbox"/> Why did they withdraw?	
	Number of Subjects Receiving Treatment (cumulative): N/A <input type="checkbox"/>	
	Number of Subjects in Post-Treatment Follow-up: N/A <input type="checkbox"/>	
	Number of Subjects that have Completed Follow-up: N/A <input type="checkbox"/>	
	Number of Subjects Included in Chart Review (Chart Review Studies ONLY): N/A <input type="checkbox"/>	
Were there any problems or complications in the study that affected the subjects or others?	<input type="checkbox"/> Yes Explain:	<input type="checkbox"/> No

Internal Serious Adverse Events		N/A <input type="checkbox"/>
Summarize all of the internal SAEs, at SJHC only, since the last approval, the action taken in response to the SAEs and any resulting changes in procedures to detect such SAEs.		
In the opinion of the Principal Investigator, is there a trend in the internal SAEs?	<input type="checkbox"/> Yes Please Describe:	<input type="checkbox"/> No
Have there been any deaths related to or not to study intervention?	<input type="checkbox"/> Yes Please Describe:	<input type="checkbox"/> No
Has there been a change in the frequency and/or severity of AEs that would result in a change to the	<input type="checkbox"/> Yes Please Describe:	<input type="checkbox"/> No

protocol or consent form?		
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Reminder
<p>1. Protocol Deviations/Violations must be reported to the REB Office. Please contact the REB Coordinator for a Protocol Deviation Form at santost@stjoe.on.ca or call X4193.</p>
<p>2. Examples of study documents or study elements that require REB approval prior to implementation:</p> <ul style="list-style-type: none"> • Recruitment Posters or Website Ads • Consent Forms • Study Procedures • Inclusion/Exclusion Criteria • Consent Process • Sample Size
<p>3. If available, please attach any final reports or publications related to this study.</p>

Principal Investigator's Signature		
Please type responses and mail this form to:		
I confirm that I have reviewed any adverse events, if applicable, in a timely fashion during the course of the study and these have been reported to the REB. All revisions to the study protocol and consent forms have been submitted for REB approval. I am not aware of any new information that may affect the continuation of the study or require change in the study protocol.		
Name of Principal Investigator:	Signature of Principal Investigator:	Date:
	REB Coordinator St. Joseph's Health Centre, Rm 7S712 30 The Queensway Toronto, ON, M6R 1B5 Email: santost@stjoe.on.ca Phone: 416-530-6486 (X 4193) Fax: 416-530-6054	
<p>(Note: the REB requires an original copy including original signature.)</p>		