MOUNT SINAI HOSPITAL

Research Ethics Board
Annual Review / Termination Form

Received Date
REB Use Only

Do Not Email, Submit typed, hard copy of this form with "Original Signature" for review to the REB office: OPG Building, 700 University Ave, Suite 8-600, Tor, ON, M5G 1Z5, Phone: (416) 586-4875.

(Use the "Tab" key to move between fields)(While cursor is in a field, use the F1 button for help)

Principal Investigator (MSH):	**MSH REB Number:**
Expiry Date of REB Approval: (DD/MMM/YYYY)	**Funding Source:** ☐ Current ☐ Revised, If revised, please provide new funding source information:
Study Title:	
Review type requested: ☐ Delegated ☐ Full Board **(submit 15 copies)** If Full Board is requested, please explain:	
Name Of Person Completing Form:	**Contact Email &Telephone #:**

STUDY ENROLMENT STATUS

☐ **NOT STARTED AT *MSH***	Reason:
For multicentre studies, have any participants been enrolled at other centres?	**PLEASE INDICATE ONE:** ☐ Close REB file ☐ Keep REB file Open
☐ **ENROLLING SUBJECTS AT *MSH***	Projected Date of Enrolment Completion: (DD/MMM/YYYY)
☐ **ENROLLMENT COMPLETE BUT STUDY IS STILL ONGOING:** (Check all that applies below) ☐ Subjects Receiving Study intervention ☐ Post-Intervention Follow-Up of Subjects (i.e., follow-up visits, data collection only) ☐ Intervention & Follow-Up Complete For All MSH Subjects - Data Clarification and/or Data Transfer Outside of MSH (i.e., sponsors or coordinating centres)	
Enrolment Termination Date: (DD/MMM/YYYY)	Duration of Follow-Up Period:
☐ **PREMATURE TERMINATION OF THE STUDY BY INVESTIGATOR OR SPONSOR**	
Termination Date: (DD/MMM/YYYY)	Number Enrolled at ***MSH***:
Reason for Termination:	**PLEASE INDICATE ONE:** ☐ Close REB file ☐ Keep REB file open
☐ **STUDY COMPLETED** (i.e., no further patient involvement/data collection, clarification & transfer outside of MSH)	
Date Closed: (DD/MMM/YYYY)	Total Enrollment at ***MSH***:
<<<<<<< **Attach a copy of a final report, if available** >>>>>>>	**PLEASE INDICATE:** ☐ Close REB file ☐ Keep REB file open

SUMMARY OF SUBJECTS AT MSH ONLY

(Complete as applicable)

Retrospective Chart Review and Tissue Studies ☐N/A

Number of charts reviewed to determine eligibility
Number of participants included in retrospective chart review study
Number of tissue samples utilized during the study

Prospective Studies ☐N/A

Number of charts reviewed for recruitment purposes to determine eligibility	
Total number of participants approved by the MSH REB to be enrolled	
Number of participants consented	
	Note: Each participant should be entered below only once so that the sum of the numbers below should be equal to the number of participants consented.
	Number of participants consented but did not meet inclusion criteria
	Number of participants consented but have not yet started the study procedures
	Number of participants who have withdrawn their consent from participation
	Number of participants receiving study intervention (e.g. study drug, questionnaires, tests, or procedures done for study purposes)
	Number of participants in post-intervention follow-up
	Number of participants that have completed the study (including completed follow up and/or withdrawn by PI) and no further contact for study purposes is planned

STUDY SUMMARY

1. PLEASE PROVIDE A BRIEF SUMMARY OF THE PROGRESS OF THE STUDY TO DATE (i.e., recruitment issues, preliminary findings, site staff changes)

2. IS THERE ANY NEW INFORMATION IN THE LITERATURE OR FROM OTHER RECENT STUDIES THAT WOULD CHANGE THE RATIONALE OR RISK/BENEFIT RATIO FOR THIS STUDY (e.g., changes in standard of care, new information about side effects, approval of another drug for this indication, etc)?

   ☐ No
   ☐ Yes
   Describe:

3. HAVE ANY PATIENTS BEEN WITHDRAWN FROM THE STUDY PREMATURELY OR WITHDRAWN CONSENT?
   ☐ No
   ☐ Yes
   Describe:

4. HAVE THERE BEEN ANY SUBJECT COMPLAINTS OR FEEDBACK ABOUT THE RESEARCH? IF YES, PLEASE DESCRIBE.

☐ No
☐ Yes
Describe:

5. BRIEFLY, SUMMARIZE ALL SERIOUS ADVERSE EVENTS (SAEs) THAT HAVE OCCURRED AT MSH ONLY SINCE THE LAST APPROVAL, ACTION TAKEN IN RESPONSE TO THE SAEs, AND ANY RESULTING CHANGES IN PROCEDURES TO DETECT SUCH SAEs.

6. HAS THERE BEEN A CHANGE IN THE FREQUENCY AND/OR SEVERITY OF ADVERSE EVENTS THAT WOULD RESULT IN A CHANGE TO THE PROTOCOL OR CONSENT FORM?

☐ No
☐ Yes
If an amendment has not been submitted, please complete and attach an Amendment Form.

7. IF APPLICABLE, HAS THERE BEEN ANY REPORT FROM THE DATA SAFETY MONITORING COMMITTEE? PLEASE INCLUDE THE MOST RECENT REPORT.

☐ No DSMB
☐ No
☐ Yes
If not yet submitted, please include the most recent report(s).

8. HAS THE STUDY NOW CHANGED TO INCLUDE COLLECTION OR BANKING OF TISSUE OR OTHER SPECIMENS (i.e., fetal tissue, placenta, blood, other body fluids)?

☐ No
☐ Yes
If an amendment has not been submitted, please complete and attach an Amendment Form.

9. SINCE THE LAST RENEWAL, HAS THERE BEEN ANY CHANGE IN THE CONFLICT OF INTEREST INFORMATION PROVIDED TO THE REB FOR INVESTIGATORS INVOLVED IN THIS STUDY? (Potential Conflicts of Interest can include functioning as an employee or consultant to the study sponsor, direct or indirect financial interest in the drug/device or technology involved in the study or receiving honorarium or other benefits from the sponsor.)

☐ No
☐ Yes
Describe:

10. IS THE CONTACT INFORMATION ON THE CONSENT FORM CURRENT?

☐ YES, CURRENT CONSENT FORM(S) ATTACHED
☐ NO, REVISED CONSENT FORM(S) ATTACHED
☐ N/A, NO CONSENT FORM(S) APPROVED FOR THIS STUDY

11. PLEASE PROVIDE A CONTACT NAME, ADDRESS, TELEPHONE NUMBER AND E-MAIL ADDRESS OF THE INDIVIDUAL TO WHOM WE SHOULD SEND STUDY CORRESPONDENCE.

NEW HEALTH RECORDS CHART RETENTION POLICY FOR STUDY SUBJECTS EFFECTIVE JULY 13th, 2005

For studies that require Health Canada approval, the research subject hospital chart must be kept for 25 years. To ensure that Health Records flags the hospital chart for retention for this time period, please advise them of the MRN by contacting Health Records (416) 586-2649

Reminder:

Attach a copy of the consent form(s) currently being used and

Retain a copy of the signed form for your records.

PRINCIPAL INVESTIGATOR'S SIGNATURE

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 form have been submitted. I am not aware of any new information that may affect the continuation of the study or require change in the study protocol.

Print Name	Signature	Date (DD/MMM/YYYY)
_____	_____	_____

Reminder:

All changes to the study protocol, consent form(s) and all other study related documents must be submitted for REB review and approval prior to implementation.