



Hôpital St-Boniface General
général Hospital

CLINICAL TRIALS PROJECT WORK SHEET

Protocol Title / Identifier: _____

Sponsor: _____

Confidentiality Agreement: yes no

Prior to the release of Protocols or product information, the Sponsor will require that the Investigator to sign a confidentiality agreement. This is a legal document stating that the Investigator (includes their staff and the institution) will not release (hard copy, verbal, soft copy) any information regarding the study to anyone without the written permission of the Sponsor. Legal penalties for releasing the information are generally stated in this document. Usually 2 originals are signed by both parties, with each keeping one original. Once the Sponsor gets their copy back, they will then release the protocol and product information.

Protocol Distribution list:

				name/date
-Principal Investigator	yes	no	N/A	_____
-Co-ordinator	yes	no	N/A	_____
-Co-Investigator(s)	yes	no	N/A	_____
-Pharmacy	yes	no	N/A	_____
-Laboratory	yes	no	N/A	_____
- _____	yes	no	N/A	_____
- _____	yes	no	N/A	_____
- _____	yes	no	N/A	_____

Investigator Brochure received: yes no N/A

An Investigator Brochure MUST be supplied for all pharmaceutical/biological studies. A package insert or product monograph is acceptable for licensed products for the licensed indication. Medical Device studies will have a Technical Manual as opposed to an IB

Investigator Agreement

Signed by Principal Investigator yes no
(generally a page of the protocol, but may be part of the Investigator Contract)

Investigator Contract

Signed by Principal Investigator yes no
Signed by Dr. Kasum yes no

(generally a multi- page document with the Indemnification statement and budget attached. A copy must be provided to the Medical Affairs/Research Office for Institutional approval)

budget	20% overhead	lab fees	REB fees	Pharmacy fees
contract	Indemnification	Investigator signature		Institution signature

Regulatory forms :

Each Investigator (PI/Co/Sub) is required to sign a 3005 form. Original 3005 are returned to the Sponsor with a signed CV and photocopy of the MDs wallet-sized medical license, photocopies are retained in the study binder. New MDs joining the study must submit their CV and 3005 PRIOR to enrolling subjects. You must be an MD with a 3005 to be eligible to enrol a patient into the study.

If the study has a US base, the Principal Investigator is required to ALSO sign a 1572 form that lists all of the co/sub-investigators. If there is a 1572, you must ALSO be an MD listed on the 1572 to be eligible to enrol a patient into the study.

Principal Investigator:	_____	3005	To Sponsor CV	License
	Name	1572		
Co-Investigator:	_____	3005	CV	License
	Name	1572		
Co-Investigator:	_____	3005	CV	License
	Name	1572		
Co-Investigator:	_____	3005	CV	License
	Name	1572		
Co-Investigator:	_____	3005	CV	License
	Name	1572		
Co-Investigator:	_____	3005	CV	License
	Name	1572		

Submission to REB

Consent revisions approved by Sponsor prior to REB submission

yes no

Documents to REB

consent	questionnaires
protocol dated : _____	advertisement
Investigator Brochure	supporting documents : _____
study budget	

REB approval granted: yes no date: _____

Copy of approval letter and correspondence submitted to Sponsor
 yes no date: _____

Submission to RRC yes no date: _____

consent	questionnaires
protocol dated : _____	advertisement
Investigator Brochure	supporting documents : _____
study budget	
approval letter from REB	

Investigator Meeting: yes no date: _____

Site start-up meeting: yes no date: _____

Advertising for participants

Arrival of study product/placebo

yes no date: _____

directed to pharmacy

Retain all packing slips. Always document the amount of product received onto the packing slip and sign/initial and date. Also document appearance of study product and packaging. If shipped on cold packs or dry ice, note temperature and condition of product (ie was it cold or frozen).

Arrival of study supplies yes no date: _____

Retain all packing slips. Always confirm the amount of supplies received onto the packing slip and sign/initial and date.

Enrolment

Ensure that you document all patients screened and then who was enrolled and who was not, including rationale for those not enrolled

Amendments

No variation from the approved protocol is permitted without an official amendment to the protocol. If the amendment affects the patient participation, then the consent form must be modified as well with both the protocol and the consent gaining approval of the REB. Amendments cannot be implemented until they are approved. Copies of the REB correspondence must also be copied to the Sponsor.

Completion of Study yes no date: _____

Send a copy of the notification of closure letter from the Sponsor to the REB

Close-out meeting yes no date: _____

Return of study product to Sponsor

yes destroyed by SBGH Pharmacy date: _____

The Sponsor is responsible to ensure that all product (including packaging) is accounted for. Do not destroy any product or product packaging unless you have written instructions from the Sponsor. Product may be destroyed only by a facility accredited to do so. Retain a copy of the letter attached to the packaging. The letter should clearly state the numbers of the product returned with a description of the product as well.

Return of supplies to Sponsor

yes no date: _____

Retain a copy of the letter attached to the packaging. The letter should clearly state the amount of supplies returned with a description of the supplies as well.

