

## SPONSOR INITIATED CLINICAL TRIAL INFORMATION FORM $Please\ submit\ this\ form\ to\ the\ Grants\ \&\ Contracts\ Coordinator, Providence\ Health\ Care\ Research\ Institute\ c/o\ \underline{gsin@providencehealth.bc.ca}.$ 1. For all other funding, please use <u>UBC Research Project Information Form (RPIF)</u>. 2. Research Ethics Board (REB)# Date Received: **Contact Information** Research Institute Principal Investigator Name: Academic Rank Faculty: Telephone: Email: Department: Address: Division: Study Coordinator/Nurse Email: Name: Facsimile: Telephone: Address: Sponsor/Legal Agreement Contact Company/ Organization Email: Contact Name: Telephone: Facsimile: Address: B. **Project Details** Study Title: Protocol/Study Nickname: Type of Study: Phase:

Does th	ne Project involve:							
	Clinical Study Drug	lo Yes Certific	cate/Application #					
	Clinical Study Device	lo Yes Certific	cate/Application #					
i)	Funding Source/Sponsor:							
ii)	CRO (if applicable):							
The account for this study will be held at (please select one):								
Pro	Providence Health Care Research Institute The University of British Columbia							
Indicate Institution (UBC, RI or formally affiliated institution) where research activity for the project will be undertaken. Select all that apply:								
_	□ UBC Vancouver Campus       □ UBC Okanagan Campus       □ BC Cancer Agency         □ BC Centre for Disease Control       □ Providence Health Care Research Institute       □ BC Mental Health & Addictions Research Institute							
_		men's Health Research Institute	<u> </u>	al Health Research Institute				
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∐ Ot	her:							
C.	Conflict of Interest							
Are you aware of any conflicts of interest that may have a bearing on this project?   No - Please proceed to Section D.								
	Yes - Please check applicable boxes below.							
i		Principal Investigator	Co-Investigator(s)	Student(s)				
	Seat on Board of Directors							
	Seat on Scientific Advisory Board							
	Any Role within the Company							
	Shares in Sponsor Company							
	License/Option Agreement							
	Non-Disclosure Agreement							
	Consulting Agreement							
		<del>-</del>						
	Other Conflicts of Interest:	<del>-</del>						
'	Other Conflicts of Interest:	<del>-</del>						
'	Other Conflicts of Interest:	<del>-</del>						
D.	Other Conflicts of Interest:  Additional Information							
<b>D.</b> i)		or information in the project?	No`	Yes - Please specify below				
i) Source	Additional Information  Will you be using any confidential materials	or information in the project?	No`	Yes - Please specify below				
i)	Additional Information  Will you be using any confidential materials	or information in the project?	No`	Yes - Please specify below				
i) Source of Materi	Additional Information  Will you be using any confidential materials	or information in the project?	No`	Yes - Please specify below				
i) Source of Materi	Additional Information  Will you be using any confidential materials  al	or information in the project?	□ No □	Yes - Please specify below				
i) Source of Materi	Additional Information  Will you be using any confidential materials  al	or information in the project?	□ No □	Yes - Please specify below				

ii)		conducting any research for another collaborator or sponsor that might No Yes-vith this project?	Please descr	ibe below			
iii)	,	employees of the collaborator or sponsor be participating in the project?	☐ No	Yes			
	If YES, wil	I they be participating on site at <b>PHC</b> or <b>UBC</b> ?	☐ No	Yes			
iv)	(Eg., a no	of this study be subcontracted by <b>the Principal Investigator</b> to a third party external to the institution? on-institutional pharmacy or lab?). Do not include study functions subcontracted by the Sponsor (ie. b arranged by Sponsor that is to be used by all sites participating in the study).	□No	Yes			
	If YES, p	please advise what part(s) of the study will be subcontracted and the name of the third party(ies).					
v)	•	personnel not employed by the institution (UBC or PHC) be part of the research team? ho is the employer of these individuals?	☐ No	Yes			
	If YES, ho	ow are the non-institutional personnel insured?					
vi)	Does any	investigator plan to publish or present the results of this study?	☐ No	Yes			
vii)		nvestigator or other personnel involved in the study been debarred or investigated by the FDA or any ulatory authority for debarment action?	☐ No	Yes			
viii)	Is there a	ny investigator involved in the study that does not have CMPA coverage?	☐ No	Yes			
	If YES, pl	ease provide additional details:					
ix)	Is there a	Is there any other information you wish to provide (eg., regarding timelines, study start up meetings, etc.)?					
E.	Signatur	es					
		institutional policies, holders of research and trust accounts must be members of the permanent academurers or research associates, if allowed by the sponsor, and at the specific request of the Dean.	nic staff. Aco	counts may			
Princip	al Investigat	or. I understand that Indirect Costs must be included in the budget as per <u>UBC Policy #87</u> .					
Signa	ture:	Date	e:				
		Please submit this form, with a copy of the study protocol and draft agreement, electronically to:  Providence Health Care Research Institute c/o <a href="mailto:gsin@providencehealth.bc.ca">gsin@providencehealth.bc.ca</a>					