SPONSOR INITIATED CLINICAL TRIAL INFORMATION FORM

Research Ethics Board (REB)#

A. Contact Information

Research Institute Principal Investigator

Name:	Academic Rank
Telephone:	Faculty:
Facsimile:	Department:
Email:	Division:
Address:	

Study Coordinator/Nurse

Name:	Email:
Telephone:	Facsimile:
Address:	

Sponsor/Legal Agreement Contact

Company/ Organization	
Contact Name:	Email:
Telephone:	Facsimile:
Address:	

B. Project Details

Study Title:

Protocol/Study Nickname:

Type of Study:

Phase:

Does the Project involve:

Clinical Study Drug ☐ No ☐ Yes Certificate/Application #

Clinical Study Device ☐ No ☐ Yes Certificate/Application #

i) Funding Source/Sponsor:

ii) CRO (if applicable):

C. Additional Information

i) Will any employees of the sponsor be participating in the project? ☐ No ☐ Yes

If YES, will they be participating on site at **VCH** or **UBC**? ☐ No ☐ Yes

ii) Will part of this study be subcontracted by **the Principal Investigator** to a third party external to the institution? *(Eg., a non-institutional pharmacy or lab?)* Do not include study functions subcontracted by the Sponsor *(ie. central lab arranged by Sponsor that is to be used by all sites participating in the study)*. ☐ No ☐ Yes

If YES, please advise what part(s) of the study will be subcontracted and the name of the third party(ies):

iii) Will any personnel not employed by the institution (UBC or VCH) be part of the research team? ☐ No ☐ Yes

If YES, who is the employer of these individuals?

If YES, how are the non-institutional personnel insured?

iv) Does any investigator plan to publish or present the results of this study? ☐ No ☐ Yes

v) Has any investigator or other personnel involved in the study been debarred or investigated by the FDA or any other regulatory authority for debarment action? ☐ No ☐ Yes

vi) Is there any investigator involved in the study that does not have CMPA coverage? ☐ No ☐ Yes

If YES, please provide additional details:

vii) Is there any other information you wish to provide (eg., regarding timelines, study start up meetings, etc.)?

viii) 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 ☐ Child & Family Research Institute

☐ Women's Health Research Institute ☐ Providence Health Care Research Institute ☐ Vancouver Coastal Health Research Institute

☐ BC Centre for Disease Control ☐ Other:

ix) The account for this study will be held at (*please select one*):

☐ Vancouver Coastal Health Authority
Please proceed to Section D

☐ The University of British Columbia
Please proceed to Section E and complete UBC Research Project Information Form (RPIF)

D. Conflict of Interest / Confidentiality

i) Are you aware of any conflicts of interest that may have a bearing on this project? ☐ No *Please proceed to Section D (ii)*

☐ Yes *Please check applicable boxes below*

	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	☐	☐	☐

Other Conflicts of Interest:

ii) Will you be using any confidential materials or information in the project? ☐ No ☐ Yes *Please specify below*

Source of Material

Nature of Material

iii) Are you conducting any research for another collaborator or sponsor that might overlap with this project? ☐ No ☐ Yes *Please specify below*

E. Signatures

In accordance with institutional policies, holders of research and trust accounts must be members of the permanent academic staff. Accounts may be opened for lecturers or research associates, if allowed by the sponsor, and at the specific request of the Dean.

Principal Investigator. I understand that Indirect Costs must be included in the budget as per UBC Policy #87.

Signature: Date:

Please submit this form, with a copy of the study protocol and draft agreement, electronically to:
Clinical Trials Administration, Vancouver Coastal Health Research Institute c/o zahra.karim@vch.ca