

## CLINICAL TRIAL SYNOPSIS FORM

<b>1. Study Information:</b> Sponsor: Protocol: Title:  1. Type of Study: <input type="checkbox"/> Clinical Trial <input type="checkbox"/> Observational Study <input type="checkbox"/> Registry Study <input type="checkbox"/> Questionnaire Study <input type="checkbox"/> Chart Review <input type="checkbox"/> Other: <input type="checkbox"/> Compassionate Use Study <input type="checkbox"/> Extension Study  2. Phase: <input type="checkbox"/> Phase I <input type="checkbox"/> Phase II <input type="checkbox"/> Phase III <input type="checkbox"/> Phase IV/Post-Market <input type="checkbox"/> Other:  3. Is this a study of a: <input type="checkbox"/> Drug <input type="checkbox"/> Device <input type="checkbox"/> Other: <input type="checkbox"/> N/A	
<b>2. Principal Investigator Information:</b> Principal Investigator's Name: Phone (and/or pager): Fax: Email: Principal Investigator's Office Address:	<b>3. Study Coordinator Information:</b> Study Coordinator's Name: Phone (and/or pager): Fax: Email: Internal Mailing Address For Documents:
<b>4. Sponsor Legal/Agreement Contact:</b>  Name: Company Name: Title: Tel: Fax: Email:	<b>6. Sponsor Financial Contact:</b> Name: Company Name: Title: Tel: Fax: Email:
<b>5. The account for this study will be held at</b> <i>(please select one):</i> <input type="checkbox"/> Vancouver Coastal Health Authority <input type="checkbox"/> The University of British Columbia	
<b>6. Additional Information:</b>  a) What is the anticipated study <b>start date</b> ? b) What is the REB meeting date? <i>(If a meeting date has not yet been assigned, please state this and email Stephanie Manusha at <a href="mailto:stephania.manusha@vch.ca">stephania.manusha@vch.ca</a> once it has.)</i>  c) Will this study be conducted at another UBC affiliated site? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span> If <b>YES</b> , please indicate the sites:  <input type="checkbox"/> Providence Health Care <input type="checkbox"/> BC Women's Hospital <input type="checkbox"/> BC Children's Hospital <input type="checkbox"/> BC Cancer Agency <input type="checkbox"/> Other:  d) Will part of this study be subcontracted <u>by the Principal Investigator</u> to a third party external to the institution? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>(E.g., a non-institutional pharmacy or lab?). Do not include study functions subcontracted by the Sponsor (i.e. central lab arranged by Sponsor that is to be used by all sites participating in the study).</i>  If YES, please advise what part(s) of the study will be subcontracted and the name of the third party(ies):  e) Will any equipment or software be received from Sponsor/CRO for use in this study? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span> If YES, please describe:  f) Will any personnel not employed by the institution (UBC or VCH) be part of the research team? <span style="float: right;"><input type="checkbox"/> Yes <input type="checkbox"/> No</span> If YES, who is the employer of these individuals: If YES, how are the non-institutional personnel insured?	

- g) Will any students or trainees be involved in the study?  Yes  No
- h) Does any investigator plan to publish or present the results of this study?  Yes  No
- i) 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?  Yes  No
- j) Is there any investigator involved in the study that does NOT have CMPA coverage?  
If yes, please provide additional details:  Yes  No
- k) Is there any other information you wish to provide (e.g., regarding timelines, study start up meeting etc.)

**7. Study Budget:**

- a) As of the date of submission of this form to the Office of Clinical Trials Administration, has the budget for this study been finalized?  Yes  No

*Once the budget has been finalized, please submit a copy of the final budget to the VCHRI Clinical Trials Administration Office.*

**8. Name, Title and Signature of Person Completing this Form:**

**Name:**

**Title:**

**Signature:** \_\_\_\_\_

Please submit this form, with a copy of the study protocol, and agreement to the VCHRI Office of Clinical Trials Administration located at the following address, or email it to: [stephania.manusha@vch.ca](mailto:stephania.manusha@vch.ca):

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V5Z 3P1  
c/o Stephania Manusha