

Policies and Guidelines for Research & Researchers at Vancouver Coastal Health Research Institute (VCHRI)

2. Industry Sponsored Clinical Trials

2.1 Scope and definition

- Sponsor initiated – Phase I, II, III, IV
- The sponsor writes the protocol and owns the compound or device.
- Agreements are negotiated and signed by sponsor, VCH, UBC and principal investigator (PI).
- Publication may be temporarily restricted (within clearly defined limits) to protect commercial interests. In the case of a multi-centre research project, publication may be restricted until the research project has been reported in full by all centres.
- Confidential information provided by the sponsor will be protected by VCH, UBC and PI.
- Particular care will be taken to include indemnification and insurance provision in the agreements.
- An overhead charge of 25% will be levied against the cost of the research project.
- Amendments to protocol must be approved by the sponsor and the Clinical Research Ethics Board (CREB)
- Amendments to clinical trial agreement are to be submitted to the attention of the VCHRI Clinical Trials Administration office.

2.2 Execution of Clinical Trial Agreement (“CTA”)

All CTAs include VCH and UBC (collectively, the institution), the PI, and the sponsor as parties to the agreement. The VCH Vice President, Research will sign on behalf of VCH and the Associate Director of the University-Industry Liaison Office will sign on behalf of UBC. All industry sponsored CTAs are executed through the VCHRI Clinical Trials Administration office.

The following documents are required:

- Contact information sheet <http://www.vchri.ca/s/FormsLogos.asp>
- Protocol
- Clinical trial agreement
- Approved budget for the research project

Once the CTA has been executed a copy will be sent to UBC and the PI.

2.3 *Obtaining approvals required to conduct research at VCH*

In order to begin an industry sponsored clinical trial, at least two approvals are required: Approval from the UBC Clinical Research Ethics Board (CREB) and Approval to Conduct Research at VCH. Go to section 4 (<http://www.vchri.ca/s/PoliciesAndGuidelines.asp#4>)