

VCHRI ACTIVE CLINICAL TRIALS DIRECTORY FAQS

http://www.vchri.ca/our-research/active-clinical-trials

1. I would like my research study posted on the VCHRI Active Clinical Trials Directory. What do I need to do?

If your research study has already been **registered** on clinicaltrials.gov, download the VCHRI <u>"Recruitment"</u> Support" Form, complete Sections 1, 2, 3e to 3g, and 5, and submit it to Wylo Kayle at wylo.kayle@vch.ca for processing. Once VCH operational research approval has been granted, the study information will be posted on the VCHRI website in the Active Clinical Trials Directory.

[NOTE: If your research study has not yet been registered on clinicaltrials.gov, but will be registered soon, please do not complete the VCHRI "Recruitment Support" Form until you receive your clinicaltrials.gov registration number.]

If your research study will **NOT be registered** on clinicaltrials.gov, you will need to download the VCHRI "Recruitment Support" Form, and complete Sections 2, 3 and 5. For non-registered studies, this Form must be submitted to the REB for review and approval prior to the posting of study information on the VCHRI website. Once the REB has approved the information on this Form, and the research study has received VCH operational research approval, the study information will be posted on the VCHRI website.

2. Where can I find the most current version of the VCHRI "Recruitment Support" Form?

Please go to the "All Forms" area of the VCHRI website: http://www.vchri.ca/forms

Scroll down to the "Clinical Trials Administration" section of this page.

3. When will my research study be posted on the VCHRI Active Clinical Trials Directory?

VCHRI will review your completed VCHRI "Recruitment Support" Form for accuracy and will ensure that the VCH Operational Research Approval for the research study is valid. VCHRI will aim to have the research study posted within three (3) business days of receiving the request or within three (3) business days of granting VCH Operational Research Approval.

[NOTE: If REB review of the VCHRI "Recruitment Support" Form is required, there will be a delay in the processing and posting time].

4. Is REB approval required in order for my research study to be posted on the VCHRI Active Clinical Trials Directory?

If the research study is or will be registered on clinicaltrials.gov, REB approval of the posting is not required.

If the research study will not be registered on clinicaltrials.gov, REB approval of the posting is required. You will be required to include details in your REB application about the VCHRI website posting in the "Recruitment Methods" section of your REB application and to submit the completed VCHRI "Recruitment Support" Form to the REB for review and approval.



5. If my study is industry sponsored or industry initiated, do I need to let the sponsor know about the VCHRI Active Clinical Trials Directory?

We are beginning to include language in our clinical trial agreements regarding the Active Clinical Trials Directory, which allows VCHRI to post registered trials and link to clinicaltrials.gov. However, as the Active Clinical Trials Directory is new, we would appreciate you mentioning the directory in your early discussions with the sponsor or CRO, as additional approval through the sponsor or CRO may be required. The "Clinical Trial Recruitment Sponsor Approval Form" may be used to obtain sponsor's separate approval, if required.

6. I understand that the research studies that are posted on the VCHRI website are linked to my VCHRI profile on the VCHRI website. How do I create a new profile or access my existing profile?

Questions regarding VCHRI researcher profiles should be directed to Vivian Sum, VCHRI Communications Manager at vivian.sum@vch.ca

7. What if I don't want my research study posted on the VCHRI Active Clinical Trials Directory?

When you complete the VCH Operational Research Approval Application Form, you have the opportunity to opt out of the posting.

8. I would like to post all of my ongoing research at VCH on the VCHRI website. Is this possible?

At this stage, we are focusing our efforts on clinical trials and research studies that are actively recruiting research participants.

Posting all types of research on the website will be considered at a later date.

9. How will you ensure that the VCHRI Active Clinical Trials Directory is kept up to date?

When you submit your VCH Annual Renewal documentation to VCHRI for review, we will confirm that the end date of the research study is updated on the website.

We will also rely on you to periodically review the Active Clinical Trials Directory and advise when a posting should be removed.