

## Clinical Trial Registration on **ClinicalTrials.gov**.

UBC Research Coordinators and Principal Investigators are now able to enter data directly onto the Clinicaltrials.gov website using the **Protocol Registration System (PRS)**. This change in procedure will streamline the process, allowing users access to **Clinicaltrials.gov** guidance notes & data-field character limits and will prevent duplication errors and back-and-forth emails to ORS.

The steps for clinical trial registration are listed below:

1. To register your trial you must first become a registered user of PRS.
2. To become a registered user you must contact the relevant administrator for UBC.

Administrators are listed below for each site:

- Children's & Women's Hospitals – Nur Eisma [neisma@cfri.ubc.ca](mailto:neisma@cfri.ubc.ca)
  - Providence/St. Paul's Hospital, BC Cancer Agency & UBC Campus – Carolyn De Melo [carolyn.demelo@ors.ubc.ca](mailto:carolyn.demelo@ors.ubc.ca)
  - Vancouver Coastal Health (including UBC Hospital) – Brit Schottelius [brit.schottelius@ors.ubc.ca](mailto:brit.schottelius@ors.ubc.ca)
3. Once your user ID is created, you will receive an email notification directly from PRS providing your user name and login information.
  4. After you receive the login information, log onto the PRS system and complete all the clinicaltrials.gov data elements and submit (click "complete" button). Please note that you are able to submit the record with errors or blank fields such as the ethics board information, oversight authority. These fields will be updated by the administrator.
  5. The PRS system notifies the administrators to login, review, approve & release the record; but it is helpful if you **email the relevant Administrator for your site**, indicating that you have completed the record
  6. The trial is published on ClinicalTrials.gov within 2-5 business days after the record is released.

Please note the following:

- Clinical Trials must be registered if your study results are to be published.
- Protocol records for active trials should be reviewed and modified as needed at least every 6 months
- Trials with "Completed" status must include *actual* completion dates, *actual* number of patients recruited & links to articles published as a result of the study.