**Registering Clinical Trials at Nova Scotia Health Authority (NSHA)**

Clinical trial registration numbers are required at NSHA for all relevant research ethics submissions. This number is a result of publicly registering the clinical trial on a recognized website ([www.clinicaltrials.gov](http://www.clinicaltrials.gov)).

**Why register a trial?**

In September 2004, the International Committee of Medical Journals Editors (ICMJE) announced that all clinical trials must be registered in a public registry in order to be considered for publication in one of eleven member journals. This policy applies to any clinical trial starting enrolment after July 1, 2005.  If enrolment in a clinical trial began prior to July 1, 2005 the ICMJE will require registration before September 13, 2005. At present, the only website which meets the ICMJE registry requirements is [www.clinicaltrials.gov](http://www.clinicaltrials.gov/)

**WhiNSHA trials require registration?**

**Phase I** trials do not need to be registered at this time

**Phase II** trials require registration if they are clinically directed.  That is, if the main purpose of the trial is to affect clinical practice or if it could shape the body of evidence about clinical effectiveness or adverse effects.  If you are not sure, we recommend you register the trial.

**Phase III** trials require registration

**Phase IV** trials require registration

**Registering a trial**

1. If the Clinical Trial is Industry or Externally Sponsored (this includes Investigator Initiated multi-center trials where the Lead Investigator/Sponsor is not at NSHA), it is the responsibility of this Sponsor to publicly register the clinical trial. Some Industry Sponsors maintain internal registry sites which produce a registration number. NSHA REB only accepts registration numbers assigned by the [www.clinicaltrials.gov](http://www.clinicaltrials.gov) site.

2. If the local PI is the Sponsor of the Clinical Trial (Investigator Initiated - He/she wrote the protocol and will be responsible for the study's initiation and management) it is his/her responsibility to also publicly register the trial at [www.clinicaltrials.gov](http://www.clinicaltrials.gov). In order to register a trial under Nova Scotia Health Authority the following is required:

                 - If you are not a registered user you must become one. To become a user, contact the Grants Coordinator at Research Services (473-4841, jennifer.thurlow@ nshealth.ca).

She will register you on the site under NSHA (The organization name on the site remains CapitalDHACanada).

                 - Once registered you will be sent a message from the website with your temporary username and password. You are now able to make changes to this information if necessary.

                 - Once you have all of the necessary login information you can enter the trial information on the website.

* the unique identification number asked for can be either your NSHA REB # or the Study Protocol Number (if applicable). If you have neither, please create a unique identifier for your trial.
* For investigator initiated research studies the **Sponsor** is the **Investigator** as defined in the drop down as **“SPONSOR INVESTIGATOR”** If an investigator has been listed as Sponsor/Investigator he/she is responsible for releasing the record once it has been approved by the NSHA PRS administrator (Jennifer Thurlow, or Lisa Underwood). NSHA is **not** the Sponsor of clinical trials.
* If the trial is Investigator Sponsored, please indicate as Sponsor/Investigator in the Sponsor tab of the record. Once the record is completed, the individual identified as the Sponsor will be contacted to approve and release the record. Please be advised that in order to be included as the Sponsor of a trial, the individual must already be a registered user under CapitalDHACanada and be included in the “Access List” of the clinicaltrials.gov record.

3. Clinicaltrials.gov is an FDA driven site; as such the definitions and requirements follow FDA regulations. Despite the fact that clinical trials at NSHA are not FDA regulated, if it is indicated that your record contains problems as per FDAAA regulations these problems do need to be addressed for your record to be considered complete and a registration number provided.

 4. Once all required information has been entered you will receive a message from the site informing you that a registration number will be assigned within 48-72 hours.

**What does a clinical trial registration number look like?**

A clinical trial which has been properly registered on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) will be assigned a number that begins with the letters NCT followed by 8 numbers

**NCT12345678**

**Study record maintenance**

All records require ongoing maintenance and attention and results must be uploaded upon completion of the study; as the study progresses please revisit your record and update as appropriate. “In general, results of an Applicable Clinical Trial of a drug, biologic, or device that is approved, licensed, or cleared by FDA must be submitted by the Responsible Party no later than 12 months after the Completion Date (see [Primary Completion Date data element](http://prsinfo.clinicaltrials.gov/definitions.html#PrimaryCompletionDate) on ClinicalTrials.gov).” **Primary Completion Date** definition: the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated. A "Type" menu is also included, with options Anticipated and Actual. For active studies, set Type to Anticipated and specify the expected completion date, updating the date as needed over the course of the study. Upon study completion, change Type to Actual and update the date if necessary. **Study Completion Date** definition: Final date on which data was (or is expected to be) collected. Use the Type menu (Anticipated/Actual) as described above.

Please ensure that projects/records being lead by medical residents have been completed and updated before the resident leaves NSHA or if a project is not completed prior to the departure of the individuals responsible for the registered record, please ensure that the contact information for the responsible party and owner of the record is updated as appropriate to ensure that the record can be completed and finalized as required.