ClinicalTrials.gov Frequently Asked Questions

General

Is there a charge for listing studies on ClinicalTrials.gov?
No, there is no charge for listing studies on ClinicalTrials.gov. ClinicalTrials.gov is a free service of the National Institutes of Health, provided through the National Library of Medicine.

How do I know if I need to register my trial?
Please refer to the Children's National CT.gov guidelines and policy documents to determine if your trial needs to be registered, and email ctgov@cnmc.org with any questions about a specific study.

Who is responsible for registering a trial?
Children's National has delegated responsibility for clinical trials registration, periodic updates, and results and adverse event reporting for investigator-initiated studies to the Principal Investigator ('Responsible Party').

When should studies be registered?
It is the policy of the Children's National that registration of trials meeting any of the criteria outlined in this Policy must be submitted to ClinicalTrials.gov concurrently with initial IRB submission. If the trial has not been registered at that time, the PI may indicate the National Clinical Trial (NCT) number is "pending" and report the NCT number immediately after obtaining from ClinicalTrials.gov. It is the responsibility of the Children's National PI to notify the IRB as soon as the NCT number has been obtained by submitting a change in research application. The Children's National PI will also be reminded at the time of the continuing review application to indicate the NCT number.

Are there penalties for failure to register a clinical trial?
It is the policy of the Children's National that failure to register your clinical trial, keep the information up to date, or submit false or misleading information could result in trial suspension and/or institutional discipline.

When will the NCT Number for my study be assigned?
The NCT Number, also called the ClinicalTrials.gov Identifier, is assigned after the protocol information has been Released (submitted) by the Responsible Party and passed review by ClinicalTrials.gov staff. At that time an e-mail notification containing the NCT Number is sent. The record, including its NCT Number, will typically be available on ClinicalTrials.gov within 2–5 business days after it is Released.

Who do I contact if I have a question about registration or my study record?
If you have questions or need help updating your record, e-mail ctgov@cnmc.org. If the question is about a specific study record, please provide the NCT Number or the Unique Protocol ID (if an NCT Number has not yet been assigned). Please include enough information about the issue so that we may better assist you. We generally respond to all e-mails within 1 business day.

Protocol Registration and Results System (PRS)

Can an organization have multiple users for a single account?
Yes. When sponsors or their representatives register to become PRS data providers, they will be given information on using PRS, including instructions for creating additional user accounts. Please contact ctgov@cnmc.org for information on how to create an account or manage your existing account(s).