

CLINICAL TRIALS REGISTRATION

Why is it necessary for clinical trials to be registered?

The International Committee of Medical Journal Editors (ICMJE) member journals will require, as a condition of consideration for publication, registration in a public clinical trials registry. For studies that are recruiting subjects after July 1, 2005, this registration must be completed before enrollment begins in order to be considered valid by the ICMJE.

Does my study need to be registered?

Studies that need to be registered are:

1. Research projects that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical intervention means any intervention used to modify a health outcome. This definition includes drugs, surgical procedures, devices, behavioural treatments, exercise programs, process-of-care changes and the like. A trial must have at least one prospectively assigned concurrent control or comparison group in order to trigger the requirement for registration.
1. Trials that have **not** already been registered by some one else (e.g. a pharmaceutical company that is funding a multi-centre trial). Trials only need to be registered once, so if the Sponsor has registered it, the individual investigators do not need to.

Where do I register my trial?

Queen's is recommending that trials be registered at the National Institutes of Health website, "Clinicaltrials.gov", which was the first website endorsed by the International Council of Medical Journal Editors (ICMJE).

How do I register my trial?

If your trial meets the criteria of 1 and 2 above, please send an email to Veronica Harris-McAllister at harrismv@kgh.kari.net with the following information:

- First and last name of the individual registering
- If the individual will be registering on behalf of a faculty member at Queen's, please provide the name of the faculty member
- email address of the individual registering

You will receive back an email including your user name and password and a link to the website where you may complete the registration process. Once you have completed your record, it will be reviewed for the required elements and then released into system.

Is the process for release of the record automatic?

No. The ICMJE and the World Health Organization (WHO) have determined a “minimal registration data set” that is required for meaningful registration of a clinical trial. The records are checked for the completion of the components of the minimal registration data set. If there is information that seems missing we will contact the researcher by follow-up email to ask that the information be completed as applicable.

When you are completing the record for your study, please pay careful attention to any prompts from the system to provide information in a given field. This is an indication of fields that are considered part of the minimal registration data set.

- [Table showing ICMJE / WHO minimal registration data set and related ClinicaTtrials.gov fields](#)

Can I re-enter my record to make revisions?

Yes. In fact, records are required to be re-verified every 6 months. Please be assured that if you re-enter your record to make revisions or updates, the initial release date is still part of the record. A re-release date will be added.

Questions?

Please contact [Veronica Harris-McAllister at harrismv@kgh.kari.net](mailto:harrismv@kgh.kari.net) or (613) 549-6666 ext. 3653 with any questions you have about this important process.