

## *Clinical Trials Registry*

### *What is the Clinical Trials Registry?*

In September 2004, the members of the International Committee of Medical Journal Editors (ICMJE) published a joint editorial ([http://www.icmje.org/clin\\_trial.pdf](http://www.icmje.org/clin_trial.pdf)) aimed at promoting registration of all clinical trials. The most recent update to the joint editorial occurred in 2010 ([http://www.icmje.org/urm\\_main.html](http://www.icmje.org/urm_main.html)). The ICMJE member journals now require, as a condition of consideration for publication, registration of all clinical trials in a public trials registry. The registration of trials must occur at or before the onset of subject enrollment into any clinical trial. In June 2007, the ICMJE adopted the World Health Organization's (WHO) definition of a clinical trial, and now defines a clinical trial as *"any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes."* Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration.

The ICMJE does not advocate one particular registry, but its member journals will require authors to register their trial in a registry that meets several criteria:

- ✓ Must be accessible to the public at no charge;
- ✓ Must be open to all prospective registrants;
- ✓ Must be managed by a not-for-profit organization;
- ✓ Must have a mechanism to ensure the validity of the registration data;
- ✓ Must be electronically searchable; and
- ✓ Must include minimum set of data elements ([http://www.icmje.org/update\\_may05.html#table1](http://www.icmje.org/update_may05.html#table1)). A clinical trial record on a registry that contains missing fields or fields that contain uninformative terminology will be considered inadequate, and failure to correct the fields will likely result in a delay or prevention of your future publications to occur.

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The ICMJE accepts registration in the following registries:

- [www.actr.org.au](http://www.actr.org.au)
- [www.clinicaltrials.gov](http://www.clinicaltrials.gov)
- [www.ISRCTN.org](http://www.ISRCTN.org)
- [www.umin.ac.jp/ctr/index/htm](http://www.umin.ac.jp/ctr/index/htm)
- <http://www.trialregister.nl/trialreg/index.asp>
- The ICMJE will also accept registration in any of the primary registries that participate in the WHO International Clinical Trials Platform (<http://www.who.int/ictrp/network/primary/en/index.html>).

### *How do I Register a Clinical Trial?*

The clinical trials registry that Queen's University and the Affiliated Teaching Hospitals (KGH, HDH, PC) support and recommend for registering clinical trials is the clinical trials registry on the National Institutes of Health's website, which was the first website endorsed by the ICMJE (<http://clinicaltrials.gov/>).

If you are Lead Investigator (of an Investigator-Initiated Study) for a single-centre or multi-centre clinical trial for any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome, then the study needs to be registered, unless the clinical trial has been already registered by someone else (e.g. a pharmaceutical company that is funding a single-centre or multi-centre trial). Clinical trials only need to be registered once, so if the Sponsor has registered the clinical trial, then the individual investigators do not need to. *However, the clinical trial must be registered by the Lead Investigator or Sponsor prior to the enrollment of any subject participating in the clinical trial.*

In order to receive a username and password for the registry, please contact Veronica Harris-McAllister, Manager of Hospital-Based Clinical Trials for the Office of Health Sciences Research at the Kingston General Hospital ([harrismv@kgh.kari.net](mailto:harrismv@kgh.kari.net) or (613) 549-6666, ext 3653). Please provide your name, department, role, email address

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and telephone contact information. Accounts can be created for both investigators and research staff for registering clinical trials on the registry, but only one individual will have ownership of the record and that individual will be solely responsible for ensuring that the registry record is up-to-date. It is a requirement that all records on the clinical registry be reviewed and updated once every six (6) months.

### *How do I Create, View or Modify a Clinical Trial Record on the Registry?*

Once an account has been created, you can log in at the following website: <https://register.clinicaltrials.gov/>. This website is used for both registering a new clinical trial record for the first time and modifying or viewing any existing record(s) previously created. You will be asked for the following information when you log on at the website:

The Organization Login is:	QueensU
Your User Name is:	<i>(assigned to you once an account is created)</i>
Your password is:	<i>(temporary password assigned but recommended to be changed once you log on for the first time)</i>


### *Creating a Record for the First Time:*

1. Click on "Create" on the main page once you have logged onto the registry. Follow along and complete all the fields. If you notice a  **WARNING** label next to a field after you have entered the information, you need to go back and complete or edit the field accordingly as it is a mandatory field that needs to be completed properly. All fields with the  **WARNING** label need to be completed according to ICMJE in order to ensure that your data is published in the future.
2. Once you have completed your record, you will need to change the record status from "In Progress" to "Complete" (at the top of the page) to release it to the administrator (Veronica Harris-McAllister) in order for it to be reviewed and released onto the registry website. Once it is released, the registry will review

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the record and assign a registry identification number if they are satisfied with the information; otherwise changes may be required before it is finally released. The approval of the clinical trial registry usually takes 2 to 5 business days.

### *Modifying/Viewing a Record:*

1. Click on “Modify” on the main page once you have logged onto the registry if you want to edit an existing record or click on “View” on the main page once you have logged onto the registry if you want to see the record only (no editing allowed in this setting).
2. If you want to modify a record, hit the “Edit” button next to the record that you want to edit.
3. At the top of the record, you will need to click on the “Reset to In-Progress” button to make any changes.
4. Make all the necessary changes to the record, including completing all the fields that contain the  **WARNING** label, and ensuring that the start/end dates, recruitment numbers, and recruitment/study status are correct.
5. Please always remember to update the “Record Verification Date” (located under the study design question) whenever you are reviewing or updating a protocol record otherwise the system does not know that you have made changes and you will get continual reminder messages to log on and update your record.
6. Once the record is completed, you will need to change the record status from “In Progress” to “Complete” (at the top of the page) to release it to the administrator (Veronica Harris-McAllister) in order for it to be reviewed and re-released back onto the registry website. By hitting “Complete” it only indicates that you have completed all your editing for the record.
7. The review of all clinical trial registry records that you own needs to be completed once every 6 months.

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*For all questions, inquiries, and assistance regarding the registering of clinical trials, please contact Veronica Harris-McAllister, Manager of Hospital-Based Clinical Trials for the Office of Health Sciences Research at the Kingston General Hospital ([harrismv@kgh.kari.net](mailto:harrismv@kgh.kari.net) or (613) 549-6666, ext 3653).*