Research Road Map

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Registering a Clinical Trial on the NIH Registry:

Researchers are responsible for ensuring that all clinical trials are registered on a public clinical trials registry. The clinical trial registry that Queen's University and its affiliated hospitals (Kingston Health Sciences Centre (KHSC) and Providence Care (PC)) support is the National Institutes of Health's (NIH) Registry: http://clinicaltrials.gov/. Clinical trials must be registered prior to the enrollment of the first research participant into the clinical trial at Queen's/KHSC/PC. Clinical trials only need to be registered once. Consequently, if a clinical trial has already been registered by the sponsor (academic or industry), the researcher does not need to register the clinical trial. Please contact Ronnie Lloyd at KHSC-KGH Site ext. 8164 or Ronnie.Lloyd@kingstonhsc.ca for further details if necessary.

WHY REGISTER A CLINICAL TRIAL?

In September 2004, the International Committee of Medical Journals Editors (ICMJE) announced that all clinical trials must be registered within a public clinical trial registry in order to be considered for publication. 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 20-item trial registration dataset (https://prsinfo.clinicaltrials.gov/trainTrainer/WHO-ICMJE-ClinTrialsgov-Cross-Ref.pdf). 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.
- ✓ Although not a required item, the ICMJE encourages authors to include a statement that indicates that the results have not yet been published in a peer-review journal, and to update the registration with the full journal citation when the results are published.

The ICMJE accepts registration in the following registries:
- www.anzctr.org.au
- www.clinicaltrials.gov
- www.ISRCTN.org
- http://www.umin.ac.jp/ctr/index.htm
- www.trialregister.nl/
- https://eudract.ema.europa.eu/

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/.

WHICH 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 Phase II trial. Phase III and IV trials require registration.

HOW TO REGISTER A NEW RECORD ON THE CLINICAL TRIAL REGISTRY?

If your clinical trial is industry-sponsored or externally-sponsored (this includes investigator-initiated multi-center trials where the lead investigator/sponsor is not a Queen's University or hospital-based (KHSC/PC) researcher), it is the responsibility of this sponsor to publicly register the clinical trial.

If the local researcher (principal investigator (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 publicly register the trial at www.clinicaltrials.gov.

If you are not a registered user on the NIH registry, you must first become one. To become a user, contact Ronnie Lloyd at KHSC-KGH Site ext. 8164 or Ronnie.Lloyd@kingstonhsc.ca. NIH registry accounts can be created for PIs, residents, and research staff/students/trainees 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. It is common for a research staff member to be the record owner while the PI ultimately has the signing authority to approve the record, similar to the TRAQ system for a TRAQ DSS FORM.

Once registered, you will be sent a message from the NIH Registry with your username and temporary password. You will be able to change your temporary password when you log onto the NIH Registry for the first time. You can request for a password reset if you forgot your password in the future. Once you have been assigned a NIH Registry username and password, you can create a new clinical trial record on the registry website. To create a new record follow the steps below:

1. Log onto https://register.clinicaltrials.gov/. Enter your assigned NIH username and password. The Organization Login is "**QueensU**".

2. Click on "Create" on the main page once you have logged onto the NIH Registry. Follow along and complete all the necessary dataset 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.

3. 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) by clicking on the button to release it to NIH Registry in order for them to review the record and release it onto the registry website once approved. Prior to going to the NIH Registry, the record will need to be reviewed and approved by the PI ("the Sponsor"). The PI needs to log onto the NIH Registry using their username and password and click on the "*Approve*" then "*Release*" button at the top of the record to move it along. If the PI is also the record owner, all three steps above must occur by the PI.

4. Once your record is approved, the NIH Registry will assign a registry identification number if they are satisfied with the information; otherwise the NIH Registry will notify you and let you know that changes are required before it is finally released onto the public domain. The approval of the record on the NIH Registry usually takes 2 to 5 business days.

Tips to Consider when Creating a New Record:

- The unique identification number asked for can be either your HSREB number or the study protocol number (if applicable). If you have neither, you will be required to create a unique identifier for your trial.

- For investigator-initiated research studies, the Sponsor is the Principal Investigator (PI). The Affiliation is Queen's University.

- If the clinical trial is investigator-initiated, please indicate this by selecting Sponsor Investigator in the Responsible Party drop down. The name entered in the Investigator field will automatically be populated in the Sponsor field. Once the record is completed, the individual identified as "the Sponsor" will be contacted to approve and release the record before it is approved by the NIH Registry: *the Protocol Registration System (PRS) Administrator*.

- Please be advised that in order to be included as the sponsor of a trial, the individual must already be a registered user on the NIH Registry (i.e. have a NIH username and password) and be included in the "*Access List*" of the clinicaltrials.gov record.

- The "*Primary Completion Date*" is the date that the final subject will be examined or receive an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated prematurely. 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.

- The "*Study Completion Date*" is the final date on which data was (or is expected to be) collected. Use the Type menu (Anticipated/Actual) as described above.

- Clinicaltrials.gov is an FDA driven site and, as such, the definitions and requirements follow FDA regulations. Despite the fact that clinical trials at Queen's/KHSC/PC are not FDA regulated (we are regulated by Health Canada), you will still need to correct any problems identified within your record as per FDA regulations, in order for your record to be considered complete by the PRS Administrator and a NIH registration number provided.

- Once all required information has been entered, you will receive a message from the NIH Registry informing you that a registration number has been assigned. This typically occurs within 2 to 5 business days, unless further updates are required.

HOW TO VIEW OR MODIFY AN EXISITING RECORD ON THE CLINICAL TRIAL REGISTRY?

To view or modify an existing record follow the steps below:

1. Log onto https://register.clinicaltrials.gov/ and enter your NIH username and password. The Organization Login is "**QueensU**".

2. Click on "*Modify*" on the main page once you have logged onto the NIH Registry if you want to edit an existing record or click on "*View*" on the main page once you have logged onto the NIH Registry if you want to see the record only (no editing allowed in this setting).

3. If you want to modify a record, hit the "*Edit*" button next to the record that you want to edit.

4. At the top of the record, you will need to click on the "*Reset to In-Progress*" button to make any changes.

5. 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.

6. 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.

7. Once the record is completed, you will need to change the record status from "*In Progress*" to "*Complete*" (at the top of the page) by clicking on the button to release it to the NIH Registry 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. Prior to going to the NIH Registry, the record will need to be reviewed and approved by the PI ("the Sponsor"). The PI needs to log onto the NIH Registry and click on the "*Approve*" then "*Release*" button at the top of the record to move it along. If the PI is also the record owner, all three steps above must occur by the PI.

8. All clinical trial registry records that you are responsible for must be reviewed and updated at least once every 6 months.

CLINCIAL TRIAL REGISTRATION NUMBER

A clinical trial which has been properly registered on the NIH Registry (www.clinicaltrials.gov) will be assigned a number that begins with the letters "NCT" followed by 8 numbers. Here is an example: NCT12345678. This is the number that you will give to the HSREB or others, if requested.

CLINCIAL TRIAL RECORD MAINTENANCE

All clinical trial 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 the "*Recruitment Status*" and "*Overall Recruitment Status*" as appropriate.   It is suggested that you revisit your record at least once every 6 months. The "*Record Verification Date*" also needs to be updated even if there are no other changes required in your record.

Please ensure that any clinical trial record led by medical residents have been completed and updated before the resident leaves Queen's University/KHSC/PC. The PI or another record holder at Queen's/KHSC/PC should be assigned and transferred ownership of the medical resident's record for maintaining the record after their departure. If a project is not completed prior to the departure of the medical resident, it is the responsible of the PI or new record owner to 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.