

# Registration Information for New Centre Participants

As new centre personnel, we hope you find the following information helpful. Should you have any questions or comments, please feel free to contact us at [roster@ctg.queensu.ca](mailto:roster@ctg.queensu.ca)

## NCIC CTG Website Access

Possession of a password does not necessarily provide access to all the protected areas of the website. Access to select areas of the website is determined by membership and/ or participation on specific studies. For some international phase III trials, for those phase III trials that are contractually restricted, access is granted only if you are on the participants list for that study. Phase I/II trials are limited participation trials by nature and therefore access to these trials is restricted to those who are included on the participants list. For access to restricted studies, you need to be on the participants list, as designated by the Principal Investigator, for that trial. Please complete the electronic [password request form](#), print, scan and email it to [roster@ctg.queensu.ca](mailto:roster@ctg.queensu.ca) or fax to (613) 533-6511. Please contact [webadmin@ctg.queensu.ca](mailto:webadmin@ctg.queensu.ca) if you have any questions. Please allow 48 hours for processing.

## **IMPORTANT**

After 48 hours from submission of a password request form confidentiality agreement, please refer to the Password Management Utility found on the main page of our website at [www.ctg.queensu.ca](http://www.ctg.queensu.ca). If your form was processed here at central office you will be able to obtain your login information using this utility even if you did not receive an initial email from us indicating your login information. You will need to know your User ID. If you do not know your User ID you can obtain it using the Find My Website User ID feature. You will need to know your centre code. If you are unable to obtain or recover your login information, please contact [webadmin@ctg.queensu.ca](mailto:webadmin@ctg.queensu.ca)

## NCIC CTG GCP Training

Education on Good Clinical Practices (GCP) is mandatory for all centre personnel participating in NCIC CTG trials who are listed on the trial participant list. **Only those centre personnel who will be involved in NCIC CTG trials are permitted to use the NCIC CTG GCP training program.** As new staff joins your centre please encourage them to complete GCP training as soon as possible. Participation on NCIC CTG trials will be put on hold until training has been completed. You must have a user id and password to access the GCP training utility. Please do not submit certificates to NCIC CTG as these are tracked electronically.

## The Trial Participant List

In accordance with ICH-GCP guidelines, the Principal Investigator for the trial will determine who will be delegated significant trial related duties and who must therefore be listed on the trial participant list. The NCIC CTG Principal/ Qualified Investigator Delegation of Study-Related Duties – Guidance for Investigators policy (at [http://www.ctg.queensu.ca/trials/generic\\_forms\\_public/PL\\_PLCF/AMG-REF-0012\\_guidance\\_for\\_investigators.pdf](http://www.ctg.queensu.ca/trials/generic_forms_public/PL_PLCF/AMG-REF-0012_guidance_for_investigators.pdf)) lists all duties the PI can delegate. Those staff who work on NCIC CTG trials, but have not been assigned significant trial related duties by the PI do not need to be listed on the trial participant list. Only those listed on the trial participant list are required to complete GCP training. Please refer to Modules & Schedules at [GCP Modules](#) to see which modules you are required to complete.

## NIH Ethics Education

Click here to see who must complete NIH ethics education [Required Ethics Education](#). NIH website at <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp> Scan and email completion certificates to [roster@ctg.queensu.ca](mailto:roster@ctg.queensu.ca) or fax to 613 533-6511 Attention Membership Roster Administrator.

## EDC/Rave Access

Individuals wanting access to the Rave Medidata utility must complete a Study Account Activation Form (SAAF), be listed on the trial participant list and must comply with all regulatory requirements (i.e. CV, GCP training, NIH ethics education, etc.) To obtain a copy of the trial specific SAAF, go to the trials webpage at <http://www.ctg.queensu.ca/trials/default.html> . Scan and email the form to [edc\\_activations@ctg.queensu.ca](mailto:edc_activations@ctg.queensu.ca) or print and fax it to (613) 533-6511.

## Investigator Registration

All investigators wishing to participate in NCIC CTG trials must meet the requirements listed below and be listed on the NCIC CTG Participant's List signed by the Principal Investigator. An investigator must be approved by NCIC CTG prior to participation in any NCIC CTG trial. Investigators may include GPOs, Clinical Associates in Oncology, Post Graduate Fellows and Nurse Practitioners. This category of investigator, referred to as Clinical Investigator (CI), is limited in the duties they may perform in the trial.

Please refer to the Principal/Qualified Investigator Delegation Of Study-Related Duties – Guidance for Investigators policy at [http://www.ctg.queensu.ca/trials/generic\\_forms\\_public/PL\\_PLCF/AMG-REF-0012\\_guidance\\_for\\_investigators.pdf](http://www.ctg.queensu.ca/trials/generic_forms_public/PL_PLCF/AMG-REF-0012_guidance_for_investigators.pdf) for more information on investigator qualifications and responsibility.

New Investigators must submit the following documentation to NCIC Clinical Trials Group:

- Submit a password request form ([Password Request Form Confidentiality Agreement](#) for website access
- Submit a current CV (please include **current hospital and university appointments**, with start/stop dates) by email to [cv@ctg.queensu.ca](mailto:cv@ctg.queensu.ca)
- Submit a certificate of completion of NIH ethics education (see above) to [roster@ctg.queensu.ca](mailto:roster@ctg.queensu.ca)
- Complete online GCP training (see above). Please do not send us copies of completion certificates.
- If planning on participating in NCI US affiliated trials, an active NCI US investigator number is required. You will see CTEP Forms on the bottom, right side of the CTEP webpage at [http://ctep.cancer.gov/investigatorResources/investigator\\_registration.htm](http://ctep.cancer.gov/investigatorResources/investigator_registration.htm)

PIs may be required to submit additional documentation. Please contact the trial team for more information.

## NCIC CTG Bulletin

A bi-weekly Bulletin is sent to all active participants in our membership roster to notify them of recent activities at Central Office, including summaries of recent trial activations/closures, upcoming meeting information, office closures, press releases, etc.

## Links

Current Trials <http://www.ctg.queensu.ca/trials/default.html>

Safety Reports [https://scoobv.ctg.queensu.ca/web\\_sae/index.php?q\\_cmd=login&q\\_hash=83a93d43dbd346849f7e68019860e009ecaa0c07](https://scoobv.ctg.queensu.ca/web_sae/index.php?q_cmd=login&q_hash=83a93d43dbd346849f7e68019860e009ecaa0c07)

Participant List Change Form & Guidance for Investigators <http://www.ctg.queensu.ca/trials/default.html>

GCP Training <http://www.ctg.queensu.ca/private/private.htm>

NIH Ethics Education <http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>

Permanent Trial Closure Listing..... <http://www.ctg.queensu.ca/trials/default.html>

Record Retention Listing ..... <http://www.ctg.queensu.ca/private/ethics/RecordsRetention.pdf>

Committees <http://www.ctg.queensu.ca/private/committees.html>

Ethics and Regulatory <http://www.ctg.queensu.ca/private/ethics/default.html>

CRA Website <http://www.ctg.queensu.ca/private/cra/default.html>