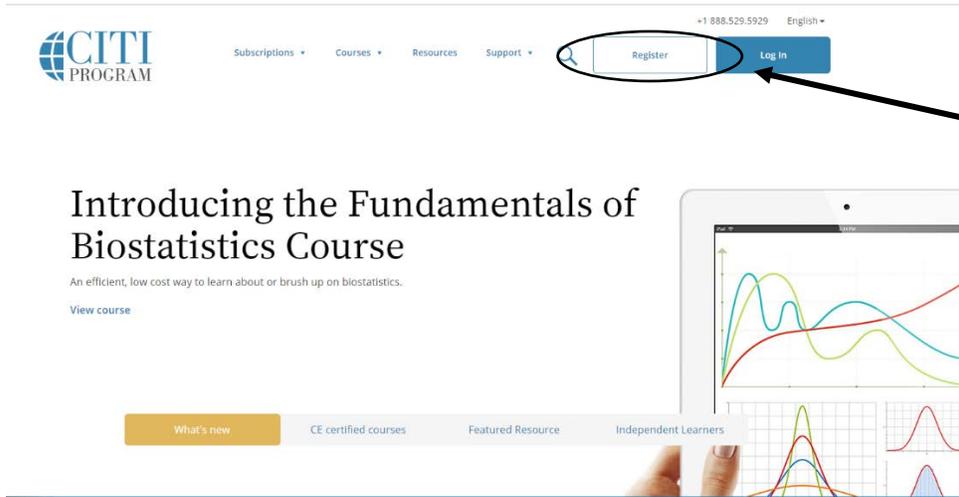# CITI Canada Training Frequently Asked Questions

1. How do I register for an account?

CITI-Canada website: www.citiprogram.org

Click on the box that says "Register"

Type in "University of Calgary" as your organization and select it when it appears in the drop down menu. Read and agree to the terms of service and confirm your affiliation with the UofC.

The next pages contain prompts for personal information, user name and password

setup. Complete all required fields as you navigate through the screens.

Choose your curriculum by clicking the course(s) you wish to take. You will be able to add or remove courses from your curriculum at any time after registration is complete.

In the next screen, you will be asked to indicate the organization(s) you are affiliated with or your role. Select all that apply. You will need to identify the affiliate organization(s) or role for each course selected in the previous screen.

In the next screen select "Finalize Registration". Shortly after registering, you will receive a confirmation email for your reference.

If you have any problems with the website or cannot remember your login info, please email linda.longpre@ucalgary.ca.

2. **How do I know which course(s) to take?**

Good Clinical Practice (GCP)
Are you conducting any "**Interventional Clinical Research**"?
A research investigation involving human participants that is designed to answer specific questions about the safety and efficacy of a biomedical intervention (drug, treatment, device) or new ways of using a known drug, treatment, or device.

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 Canada Division 5
Are you involved in an "**Interventional Drug Study**"?
A clinical trial utilizing an investigational product (including biologics, radiopharmaceuticals or natural health product). Includes any substance or mixture of substances manufactured, sold or represented for use in:
- diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
- restoring, correcting or modifying organic functions in human beings or animals, or
- disinfection in premises in which food is manufactured, prepared or kept.

If your project is considered an interventional drug study, you are required to complete both the GCP and the Health Canada Division 5 training.

3. **What is the CITI Canada Program?**

   The CITI-Canada Program offers comprehensive courses on a variety of research related matters. The courses include a quiz after each module to test the learner's knowledge. Following successful completion of the course, the learner is able to obtain a completion certificate. The certificates can be added to your training records to show evidence of training.

4. **Why has the University chosen the CITI Canada courses?**

   "TransCelerate BioPharma", which represents a number of biopharmaceutical companies, has recognized that the CITI Canada Good Clinical Practice course meets their criteria for ICH GCP training for investigator site personnel. Many biopharmaceutical companies as well as research networks, hospitals and universities accept the CITI Canada GCP course as their gold standard.

5. **How long are the GCP and Health Canada Division 5 courses and what do they cover?**

   Good Clinical Practice (GCP)

   Time required for course completion ranges from 3-6 hours depending on your familiarity with research principles. You do not have to complete the training in one sitting, you can start and stop the training as often as you wish.

   This course is a 10-module program that discusses good clinical practice as it relates to clinical trials of both drugs/biologics as well as devices. The discussion is focused on all applicable regulations in Canada such as Health Canada-Division 5, The Tri-Council Policy Statement 2, the U.S. Food and Drug Administration (U.S. FDA) regulatory requirements, and the International Conference on Harmonisation (ICH)-E6 guidelines, which were adopted to aid in compliance with regulatory requirements of the multiple government agencies. Modules cover topics such as: Overview of New Drug Development; Health Canada, FDA Regulated Research and ICH for Investigators; Investigator Obligations in Health Canada and FDA-Regulated Clinical Research, and Informed Consent.

   Health Canada Division 5

   Time required for course completion ranges from 2-4 hours depending on your familiarity with regulations. You do not have to complete the training in one sitting, you can start and stop the training as often as you wish.

   The *Food and Drugs Act* and the *Food and Drug Regulations* govern the sale and importation of drugs for use in human clinical trials in Canada. Specifically, Part C, Division 5 of the *Regulations* addresses drugs for clinical trials involving human participants. Health Canada tells us that the Qualified Investigator must ensure

compliance with the *Regulations* and the International Conference on Harmonisation Good Clinical Practice (ICH-GCP E6) Guideline (incorporated in the Regulations) from every person involved in the conduct of the clinical trial at their site. To that end, there should be evidence of satisfactory training of personnel involved in these processes. The successful completion of this CITI-Canada course can be used as evidence of training in Division 5 *Regulations*. This "Division 5" course covers all research conducted under Division 5 *Regulations* and it provides practical solutions and methods for complying with the *Regulations*.

6. **Do the CITI Programs expire?**

   Once you have trained on the CITI Good Clinical Practice course, the University considers you trained.

   As many Sponsors require that certification in GCP be regularly renewed, you will receive a reminder email at 3 years following the date that training was completed. You will be responsible for renewing your GCP training should your Sponsor or Sponsors require it.

   At present, Health Canada Division 5 training does not expire.

   Please note: we may be required to revisit the expiry dates should the regulations change.

7. **What if I received training elsewhere?**

   If you have completed your CITI GCP training elsewhere, please upload your certificate to your IRISS Researcher Profile.

   For individuals who have already taken the CITI-Canada training program at another institution (e.g. UofA, AHS, etc.) and want to share your information with other organizations, you can do so from the CITI-Canada Main Menu. Click on the "*Click here to affiliate with another institution*" link and follow the prompts. You will need to select each course you wish to share with the new institution. Note, if the record indicates incomplete, this means that you need to take an additional module required by the newly affiliated institution.

8. **How to add/change your affiliated institution or transfer completions?**

   The steps below will assist you if you have mistakenly chosen the wrong institution, your institution has changed, or you have an affiliation with more than one institution.

- From the Main Menu on your profile click on the link "Click here to affiliate with another institution."

- Type and choose the correct institution from the search box.
- Answer the member information questions required by your newly affiliated institution.
- Enroll in the course(s) required by your newly affiliated institution.

  If you would like to receive credit for modules previously taken, there are several requirements that must be met.

- To transfer course credit between institutions, you will need to be affiliated with both institutions (your previous institution and your new institution). Follow the "Click here to affiliate with another institution" link on your Main Menu to add an affiliation.

- When you are affiliated with both institutions, enroll in the courses that need to be transferred under both institutions, via the "Add a Course or Update Learner Groups" link under the appropriate institution if necessary. You will need to enroll in the same stage of the course (Basic / Refresher) for a proper transfer to occur.

- Once you are enrolled in the courses, any modules that are shared between the courses between institutions will have their credit transferred automatically. The transfer is based on each module's unique ID number. If the courses do not match exactly, not all credit will transfer and you may need complete the difference in modules at your new institution to get full credit for a Completion Report.

9. **How do I upload my certificate in my IRISS Researcher Profile?**

Once you complete the training, you are required to upload the training certificate(s) to your researcher profile in IRISS. Please follow the Guidance document for updating your researcher profile. For further assistance, you may contact iriss.support@ucalgary.ca.