Clinical Research Training Manual for ReDA

Contents

Lawson Training Requirements Matrix

As a requirement for Lawson Approval, training and education in clinical research must be demonstrated. Training is required based on the type of study being conducted and each individual's role within the study.

All persons who are conducting clinical research at any of Lawson's research sites or that are part of Lawson's clinical research community must comply with the Quality Assurance and Education Program training requirements. This will generally be inclusive of the following roles:

Clinical Research Investigators	**Clinical Research Team (Coordinators/Personnel)**	**Clinical Research Support**
Sponsor-Investigators Qualified Investigators (as defined in the Regulations Principal, Co-, Sub-, and Additional Investigators	Coordinators Associates Assistants Research Pharmacists and Pharmacy Technicians	Administration Clinical Pharmacists and Pharmacy Technicians Other Clinical Research Support Departments (e.g. Microbiology, Pathology, pulmonary function testing, respiratory therapy, diagnostic imaging, etc.)

**** Note:*** Clinical Research support team members do not need to be listed under the ReDA stakeholders tab or WREM section 1.4 other study team members.

Types of Studies

Non-Regulated: A study that is *not* regulated by Health Canada; e.g., the study is not being conducted under a Clinical Trial Application (investigational or off-label drug or natural health product) or Investigational Testing Authorization (investigational or off-label medical device).

Health Canada Regulated Drug/Natural Health Product (NHP), Local Principal Investigator (PI) Participating Site: A study involving an investigational or off-label drug or natural health product that is being conducted under a Clinical Trial Application (CTA) where the local Principal Investigator is not the Sponsor. A pharmaceutical company, another research institution or an investigator at another institution may be the Sponsor.

Health Canada Regulated Drug/NHP, Local PI is the Sponsor: A study involving an investigational or off-label drug or natural health product that is being conducted under a Clinical Trial Application (CTA) where the local Principal Investigator is also the Sponsor, known as the Sponsor-Investigator.

Health Canada Regulated Medical Device: A study involving an investigational or off-label medical device that is being conducted under an Investigational Testing Authorization (ITA).

Interpreting the Clinical Research Training Requirements Matrix

Mandatory training is required based on the type of study being conducted. To obtain Lawson Approval, the Principal Investigator's training must be current and up-to-date.

Training requirements for other members of the research team and clinical research (CR) support staff are outlined in the matrix and may be Mandatory (M), Recommended (R) or Optional (O). It is the responsibility of the Principal Investigator to ensure that the research team has completed the required training prior to any delegated tasks being performed.

Proof of training must be on file for all members of the research team and includes but is not limited to: FRM008 (prior to July 2017), certificates, completion reports, etc. Proof of training may be required upon request by Lawson.

✓ = Required	**M = Mandatory (training must be successfully completed prior to performing task)**	**R = Recommended (training is at the discretion of the PI)**	**O = Optional (training is at the discretion of the individual/PI)**

TRAINING MODULES	**TYPE OF STUDY**				**ROLE**	
	Non-Regulated	**Health Canada Regulated**			**Investigators / Research Team***	**CR Support ****
		Drug/NHP Local PI Participating Site	Drug/NHP Local PI is the Sponsor	Medical Device		
Tri-Council Policy Statement (TCPS2)	✓	✓	✓	✓	M	O
Lawson SOP Module	✓	✓	✓	✓	M	R
Good Clinical Practice (GCP)		✓	✓	✓	M	O
Health Canada, Food & Drug Regulations, Part C, Division 5			✓		M	O
Transportation of Dangerous Goods	Mandatory for delegated team member if biological samples are being shipped offsite.					

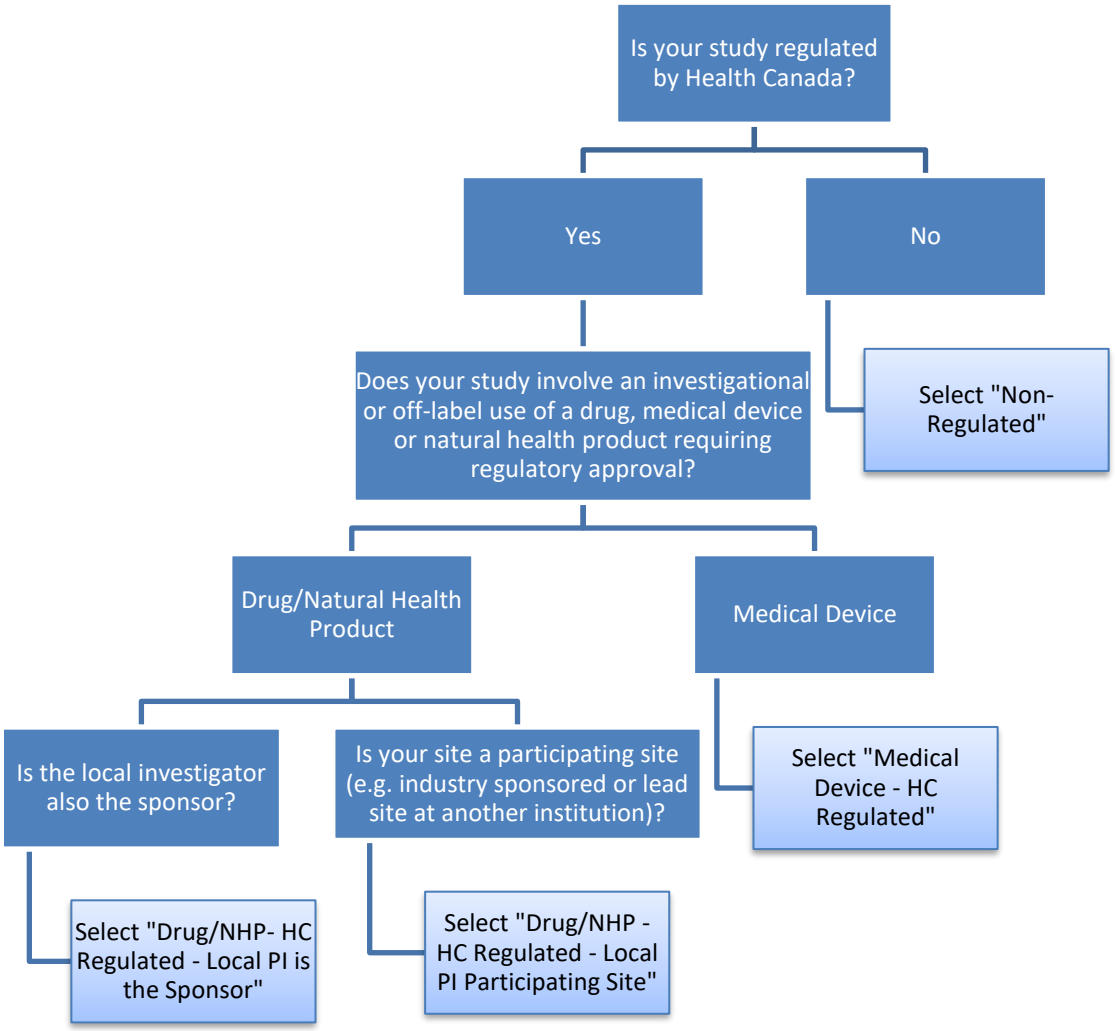
* The Sponsor may require additional training for the investigator or members of the research team.

**Clinical staff designated as CR support are not considered part of the research team. If clinical staff are required to perform a specialized protocol procedure that is deemed above standard of care, they should be identified as such and additional training will apply. In these cases, the PI should identify and

delegate responsibilities to one individual at the time of study initiation, and this person will be responsible for performing that procedure for all research participants in the study. Any further clarification of this process should be directed to Lawson's Quality Assurance and Education team at Ext. 72377 or qaep@lawsonresearch.com

*** Although the regulations for using natural health products in clinical trials are under Part 4 of the Natural Health Product Regulations, not under Division 5 (Drugs) of the Food and Drugs Regulations, the CITI training module for Division 5 details sponsor responsibilities including reporting requirements; which are the same between these directorates.

Determining Study Categorization (Training) at ReDA Submission – Project Information Tab



Determining What Training Is Outstanding for a Pending Study

1) Find your study in ReDA through the **ReDA Study Search** tile in the main Work Area
2) Click on the **ReDA ID** for your project
3) Click on the **Stakeholders** tab, under Study Details
4) If there is a red "X" next to your name, training is not up-to-date in ReDA. Click on the "X" to view what needs to be completed and/or updated. If you have a green checkmark next to your name, your training requirements have been met for this study and ReDA is up-to-date with current training information.

   IMPORTANT NOTE: Your training may be complete, but not up-to-date in ReDA. When training is complete, ReDA does *not* automatically update. Please review your training profile in the applicable platform to confirm if training is outstanding.
5) When you click on the "X" or checkmark, a table will pop-up. The **Training Date Expiry** column will indicate if training has not been completed or if it has expired.

For screenshots, refer to Appendix 1.

Clinical Research Training

Tri-Council Policy Statement (TCPS2) Training

The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* is a joint policy of Canada's three federal research agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC) and the Social Sciences and Humanities Research Council of Canada (SSHRC). This training takes approximately 3 hours to complete.

Complete the training module at the Government of Canada TCPS2: CORE (Course on Research Ethics) website: https://tcps2core.ca/login

To complete the TCPS2 training, steps are as follows:

1) Click **Create New Account**
2) Complete registration fields. Affiliate with **Lawson Health Research Institute**
3) Click **Register**
4) An activation email is sent to the email address provided. Click on the link in the email to activate your account.
5) Proceed to the log in page to begin the tutorial.

6) The module takes approximately 3 hours to complete. Your progress in the module is automatically saved, so you may choose to complete the module over several days.
7) Once you have completed the module, print your certificate. Retain the certificate for your records.

**** Note:*** If you completed this training while at another institution, it does not need to be repeated. Your training certificate will be requested by Lawson to obtain the date of completion.

Standard Operating Procedure (SOP) Training

In July 2017, Lawson's Quality Assurance and Education team launched an e-Learning module for SOP training. The module encompasses all of the SOPs and must be completed every three years. The module is available on the hospital learning platforms: MyEducation, iLearn and LearningEdge. Individuals who do not have access to any of these platforms may complete the training via external link. You must save a copy of your SOP training certificate for your research records.

SOP Training takes approximately 50 minutes to complete.

SOP Training for Physicians, Fellows, Residents and Schulich Medical Students

Refer to Appendix 2 for MyEducation instructions.

SOP Training for LHSC Staff

Refer to Appendix 3 for iLearn instructions.

SOP Training for St. Joseph's Staff

Refer to Appendix 4 for LearningEdge instructions.

SOP Training Instructions for External Link

Refer to Appendix 5 for instructions.

Collaborative Institutional Training Initiate (CITI) Training Modules

The following training modules should be completed though CITI (as per the Training Matrix):

- Good Clinical Practice;
- Health Canada Division 5; and
- Transportation of Dangerous Goods

Registering and Adding Courses

1) Visit the CITI website at https://www.citiprogram.org/
2) Click **Register**
3) Affiliate with **Lawson Health Research Institute**

4) Click **Continue** to Step 2, 3 etc.
5) Under the **Institutional Courses** section, click **View Courses**
6) In the **Learner Tools for Lawson Health Research Institute (N2)** section, click **Add a Course**
7) Check the box(es) next to the course(s) you need to take and click **Next**
8) In the **Courses Ready to Begin** section, click **Start Now** next to the course you are ready to complete.
9) Complete the modules required for each course. A passing score of 80% is needed for successful completion.

Refer to Appendix 6 for screenshots.

Printing Completion Reports/Certificates

1) Log in to CITI https://www.citiprogram.org/
2) Click **Records** in the top menu
3) Find the course for which you need to obtain the certificate or completion report. **Completion Record** is the final column in the table; click **View-Print-Share** under this column to view the completion report or certificate. These should be saved electronically or printed and stored with the study files.

Refer to Appendix 7 for screenshots.

Good Clinical Practice (GCP) Training

This training is valid for three years (**if completed after 04Sep2019; refer to the expiry date on the certificate**) and is required if conducting research regulated by Health Canada (i.e. involving an investigational or off-label drug, medical device or natural health product). After three years, refresher training is required. The full course is required again after the refresher course is completed twice (i.e., every 9 years).

The full GCP course takes approximately 5 hours to complete. The refresher course takes approximately 2 hours to complete.

Health Canada, Part C Division 5 Training

This training is valid for three years (**if completed after 04Sep2019; refer to the expiry date on the certificate**) and is required if the local PI is the sponsor of a study involving an investigational or off-label drug or natural health product.

This training takes approximately 2 hours to complete.

Transportation of Dangerous Goods (TDG) Training

This training is valid for two years. Lawson will provide a signed certificate of completion for hospital employees. This certificate may be requested by the courier when shipping dangerous goods by land (TDG) or air (IATA). Western staff, faculty, students will need to affiliate with Western when registering and a certificate will be provided by Western University.

This training takes approximately 3 hours to complete.

After Training is Complete

Once your training is current and complete, Lawson will update your training profile in the Research Passport and Courses tab in ReDA (under Contact Details in your profile) based on weekly completion reports from the applicable learning systems.

If PI training is the last piece needed for Lawson Approval, please notify **Lawson Approvals** as soon as this training is completed and we will update ReDA immediately to avoid any delays in issuing Lawson Approval for your study.

If you have affiliated with another institution, such as Western University, to complete certain training modules - Lawson will not be able to access your completed training. Lawson will request proof of training via certificate as required to update your training information in ReDA.

Contact Information

For more information about training links, instructions or issues with completing your training; contact the Quality Assurance and Education team.

Email: qaep@lawsonresearch.com

Phone: (519)685-8500 Ext. 72377

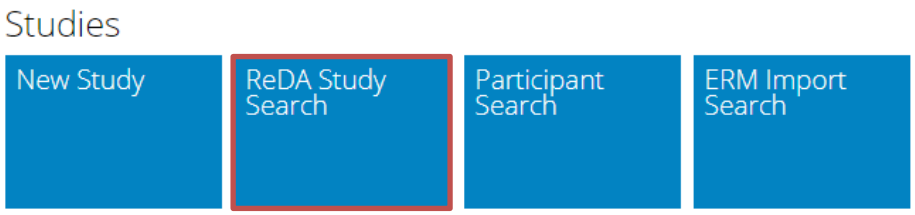
For more information about ReDA/updating your training profilein ReDA and LORA; contact the Lawson Approval team.

Email: lawsonapproval@lawsonresearch.com

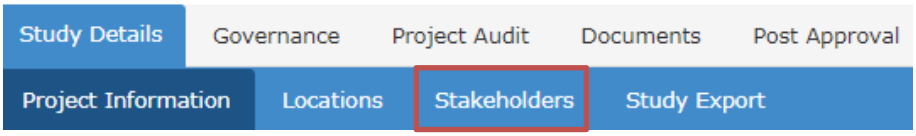
Phone: (519)685-8500 Ext. 72378

Appendix 1: Determining What Training Is Outstanding for a Pending Study

1) Find your study in ReDA through the **ReDA Study Search** tile



2) Click on the **ReDA ID**
3) Click on the **Stakeholders** tab



4) If there is a red "X" next to your name, training is not up-to-date in ReDA. Click on the "X" to view what needs to be completed and/or updated. If you have a green checkmark next to your name, your training requirements have been met for this study and ReDA is up-to-date with current training information.

   IMPORTANT NOTE: Your training may be complete, but not up-to-date in ReDA. When training is complete, ReDA does *not* automatically update. Please review your training profile in the applicable platform to confirm if training is outstanding.

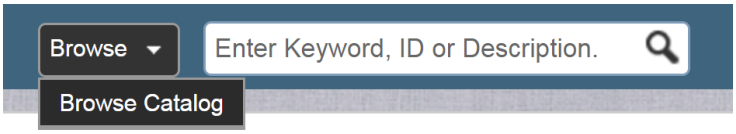
5) When you click on the "X" or checkmark, a table will pop-up. The **Training Date Expiry** column will indicate if training has not been completed or if it has expired.

Training Required	Training Expiry Date
Lawson SOP Module	NOT COMPLETED
Privacy	EXPIRED ON 21/07/2018
TCPS2	01/01/2099

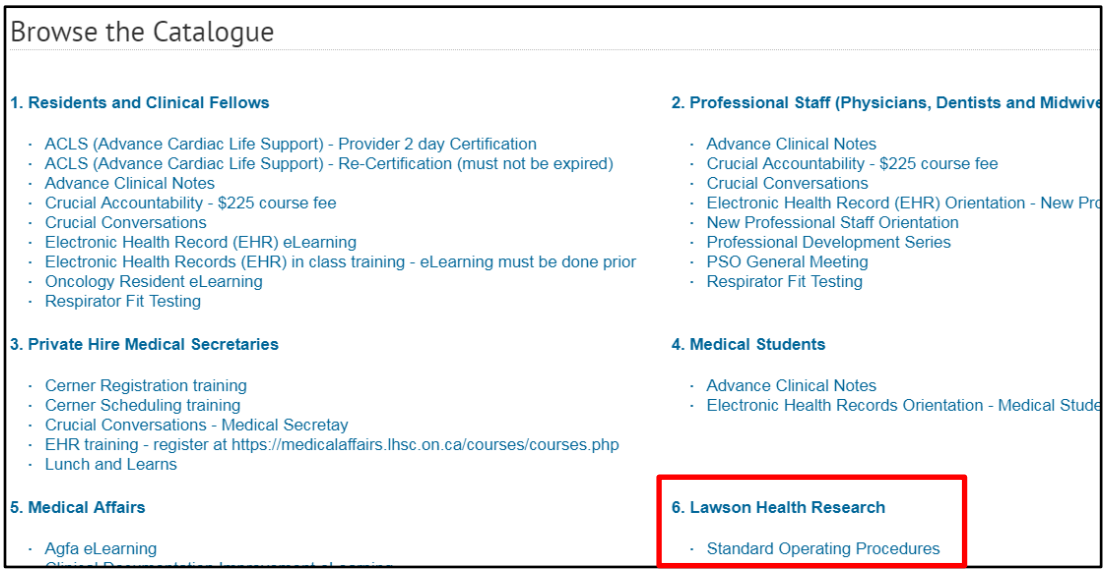
Close

Appendix 2: SOP Training Instructions for MyEducation

1) Login to MyEducation at the following link: https://ilearn.lhsc.on.ca/Saba/Web/Main (Google Chrome and Internet Explorer browsers are recommended)
2) Click the dropdown arrow next to **Browse**
3) Click **Browse Catalogue**



4) Click on **Standard Operating Procedures** under the **Lawson Health Research** heading



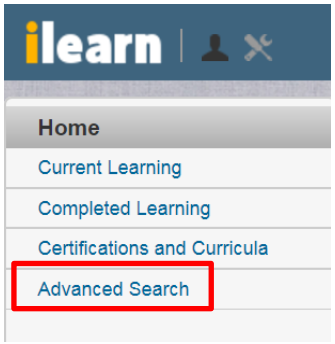
5) Click **Actions**
6) Click **Register**

7) Module will launch
8) Complete training and save a copy of your SOP training certificate for your research records

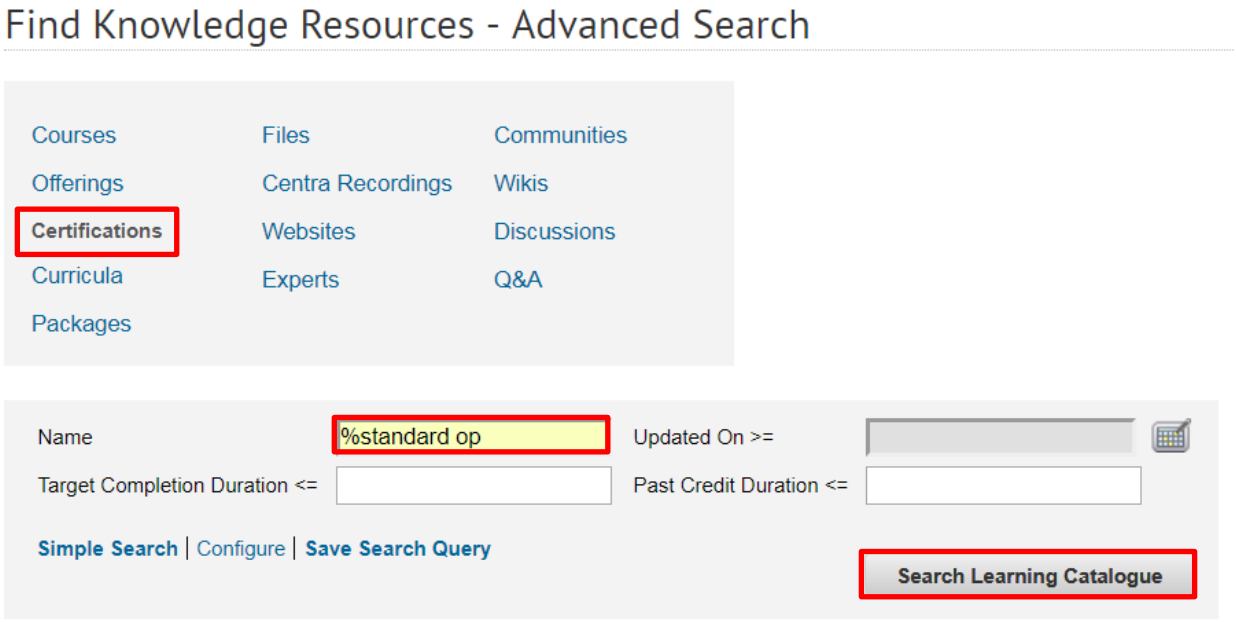
NOTE: Once you have registered and completed the certification, you will be automatically reminded by the system to re-certify your training in 3 years

Appendix 3: SOP Training Instructions for iLearn

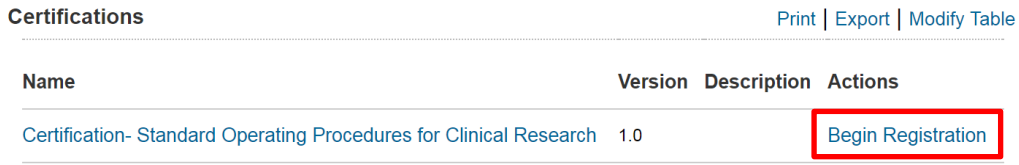
1) Log in to iLearn at the following link: https://ilearn.lhsc.on.ca/Saba/Web/Main
   (Google Chrome and Internet Explorer browsers are recommended)
2) Click on the **Advanced Search** menu item



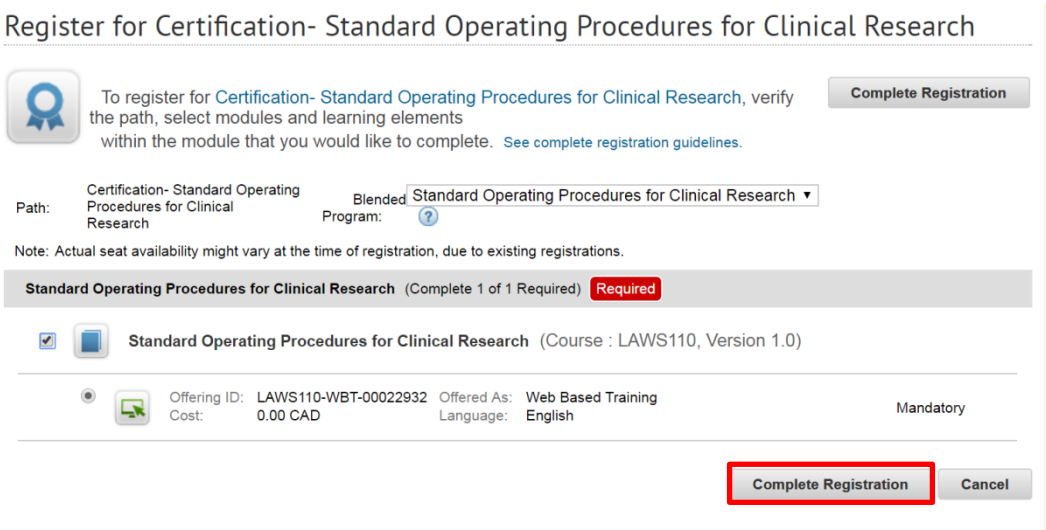
3) Click **Certifications**
4) Type a percent sign and part of the name of the certification in the **Name** field
   e.g. **%standard op**
5) Click the **Search Learning Catalogue** button



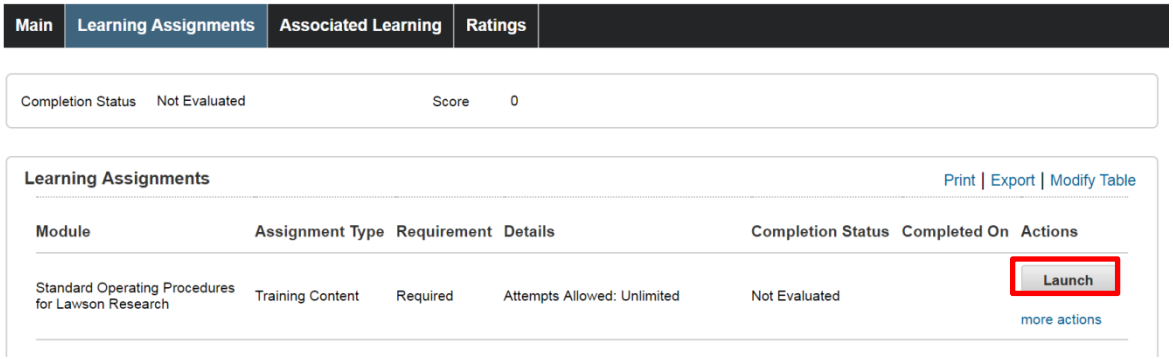
6) Click **Begin Registration**



7) Click **Complete Registration**



The module should automatically begin, if it doesn't click **Launch**

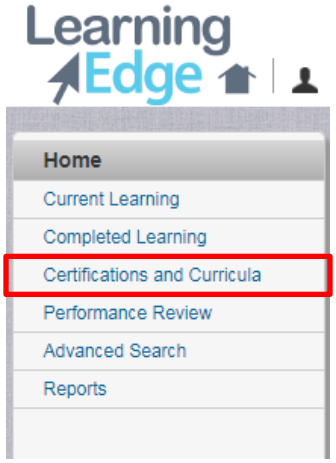


9) Complete training and save a copy of your SOP training certificate for your research records

NOTE: Once you have registered and completed the certification, you will be automatically reminded by the system to re-certify your training in 3 years

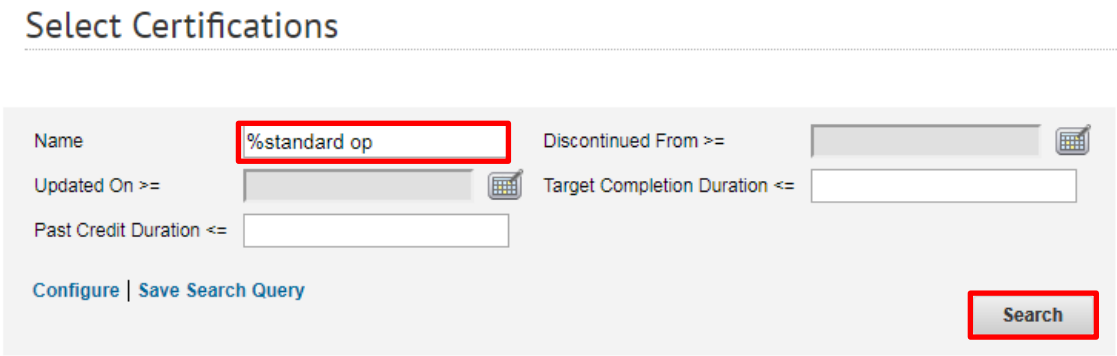
Appendix 4: SOP Training Instructions for LearningEdge

1) Log in to LearningEdge at the following link:
   https://learningedge.sjhc.london.on.ca/Saba/Web/Main
   (Google Chrome and Internet Explorer browsers are recommended)
2) Click on the **Certifications and Curricula** menu item

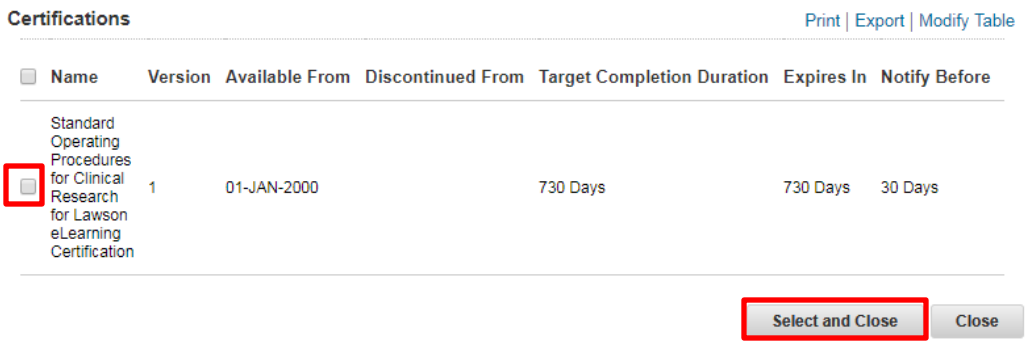


3) Click the **Add Certifications** link

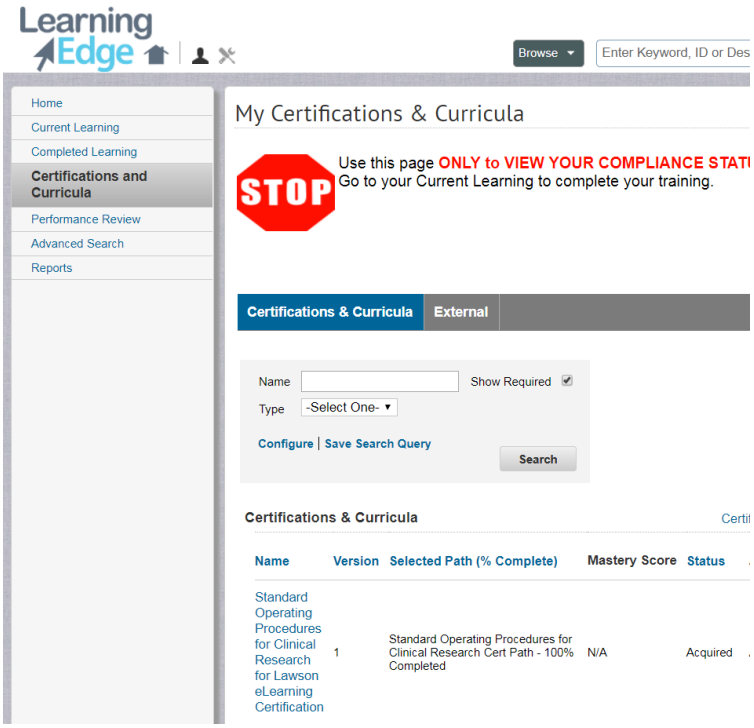
4) Type a percent sign and part of the name of the certification **%standard op**
5) Click the **Search** button



6) Click the checkbox adjacent to the certification to add
7) Click the **Select and Close** button



8) View the certification list to validate that the certification has been added and check the status



9) Complete training and save a copy of your SOP training certificate for your research records

NOTE: If you have previously completed the learning required to qualify for the certification, your status will automatically be set as **Acquired**. You **will not be required** to repeat the previously completed learning. Once you have registered and completed the certification, you will be automatically reminded by the system to re-certify your training in 3 years

Appendix 5: SOP Training Instructions for External Link

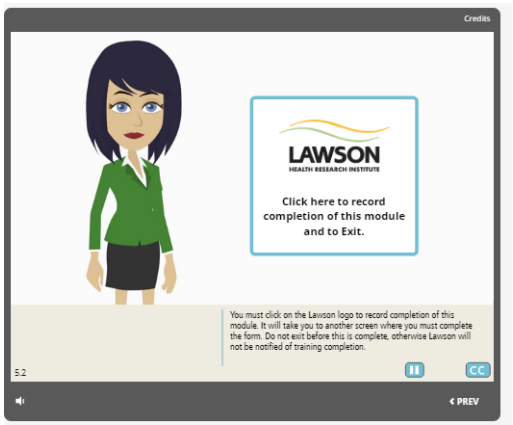
NOTE: Only use to external link if you do not have access to the hospital eLearning system(s). You will not be automatically notified when SOP training is due to re-certify (every 3 years).

1) Access the module at the following link: https://apps.sjhc.london.on.ca/sj_files/studentaffairs/SOPS_Clinical_Research/story.html (Google Chrome and Internet Explorer browsers are recommended)

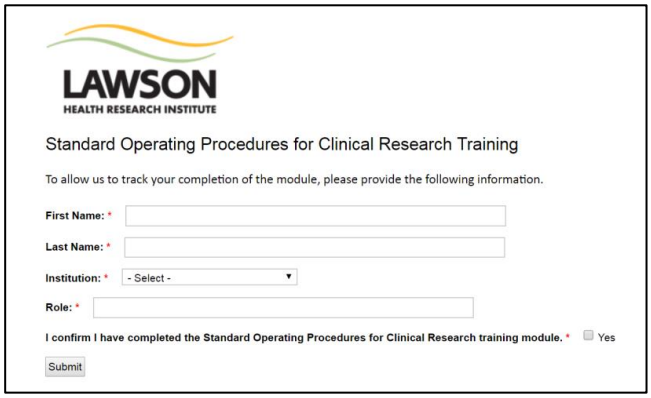
2) You must complete the module in one session. **Your progress will not be tracked once you exit.**

3) Once the module is complete, **save/print a copy of the certificate immediately**. You will not be able to access the certificate again once you exit. Your certificate is considered proof of training and must be filed with the study documents.

4) **IMPORTANT:** When you arrive at the page in the screenshot below, click the Lawson logo. This will bring you to a webform where you need to enter your information so that Lawson is informed of your training completion.



5) Complete the information in the webform. The purpose is for Lawson to track your completion of the SOP training module.

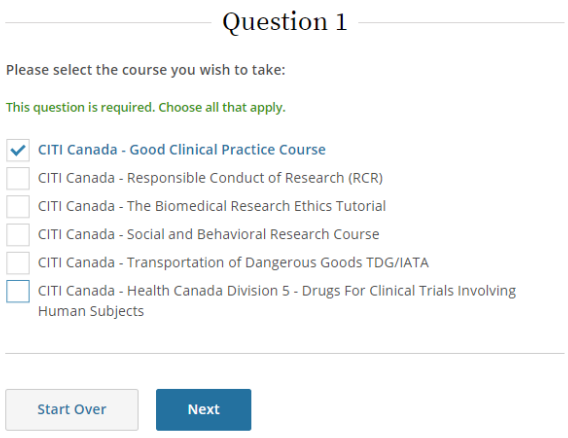


Appendix 6: Registering and Adding Courses in CITI

1) Visit the CITI website at https://www.citiprogram.org/
2) Click **Register**
3) Affiliate with Lawson Health Research Institute
4) Click **Continue** to Step 2, 3 etc.
5) Under the **Institutional Courses** section, click **View Courses**

6) In the **Learner Tools for Lawson Health Research Institute (N2)** section, click **Add a Course**

7) Check the box(es) next to the course(s) you need to take and click **Next**



8) In the **Courses Ready to Begin** section, click **Start Now** next to the course you are ready to complete.

9) Complete the modules required for each course. A passing score of 80% is needed for successful completion.

Appendix 7: Printing Completion Reports/Certificates in CITI

1) Log in to CITI https://www.citiprogram.org/
2) Click **Records** in the top menu

3) Find the course for which you need to obtain the certificate or completion report. **Completion Record** is the final column in the table; click **View-Print-Share** under this column to view the completion report or certificate. These should be saved electronically or printed and stored with the study files.

Canada GCP (ID 42986)

Stage	Record ID	Passing Score	Your Score	Start Date	Completion Date	Expiration Date	Gradebook	Completion Record
BASIC	15634739	80%	91%	25-Mar-2015	25-Mar-2015	24-Mar-2017	View	View-Print-Share
Refresher	22481901	80%	97%	24-Mar-2017	24-Mar-2017	24-Mar-2019	View	View-Print-Share