CCTG

RIPPLE USER GUIDE

Version: 6.0 2018OCT19

Canadian Cancer Trials Group

Queen's University

Kingston, ON

Canada K7L 3N6

Canadian Cancer Trials Group

Table of Contents

1 INTRODUCTION

The Roster Interface Program & Participants List Environment (RIPPLE) is a web-based utility where CCTG Members can:

- Request new CCTG membership accounts
- Manage CCTG membership accounts
- Create and manage trial Participants List (list of personnel at your site that are working on a trial)
- Document the Qualified Investigator's (QI's) delegation of significant trial related duties.
- Review required documentation / credentials (e.g., Good Clinical Practice (GCP) training etc.)
- Upload required documents
- Produce membership or participants list reports

This user guide provides an overview of the key functions associated with each component of RIPPLE.

- Membership Accounts
- Centre Affiliation
- Participant Signature Form
- RIPPLE Roles (RRA/PLA/PLD)
- Participants List

Additional resources are available using the 'Resource' link found on the top right corner of the RIPPLE main page. Questions regarding RIPPLE can be emailed to RIPPLE@ctg.queensu.ca.

RIPPLE can be accessed via the CCTG homepage

- Click on the ***CCTG Toolbox***
- Under ***Applications*** click on ***RIPPLE***
- Log in using your CCTG Member User ID and password

2 ACRONYMS

ACRA: Additional Clinical Research Associate

ECRA: Ethics Clinical Research Associate

EDC: Electronic Data Capture

GAO: Group Administrator Office

GCP: Good Clinical Practice

OCO: Office of Compliance and Oversight

PCRA: Principal Clinical Research Associate

PL: Participants List

PLA: Participants List Administrator

PLCF: Participants List Change Form

PLD: Participants List Delegate

PPHARM: Principal Pharmacist

PSF: Participants Signature Form

QI: Qualified Investigator

RIPPLE: Roster Interface Program & Participants List Environment

RRA: Remote Roster Administrator

STU: Site Training Utility

TSR: Trial Signature Report

3 MEMBERSHIP ACCOUNTS

3.1 Remote Roster Administrator (RRA)

An RRA is a centre staff member designated by the centre to administer the centre's membership roster (including approving new members at their centre).

In addition to making changes and approvals in the membership roster, the RRA can create and update all trial Participants Lists at their centre in RIPPLE. The RRA can also select additional personnel at their centre to function as Participants List Administrators (PLAs) or Participant List Delegates (PLDs). Please note that a PLD must accept the assignment of the role, and after their acceptance the PLDs must be approved by the trial QI. PLD removals must also be approved by the QI. Please refer to Appendix I for a table that summarizes all of the RIPPLE roles.

For coverage purposes each site must designate a minimum of 2 RRAs. The maximum number that a site can have is 3.

3.1.1 Assigning an RRA

- Access RIPPLE via the Canadian Cancer Trials Group ***Toolbox***
- Click ***Resources*** in the top right corner of the webpage
- Select and download the **Remote Roster Administrator (RRA) Designation Form**
- Complete and follow the submission instructions at the bottom of the form (Note: the Designation Form must be signed by your Centre Representative)

3.1.2 Registering a New CCTG Membership Account

A new membership account can be created by a centre's RRA or by the new member themselves.

3.1.3 Registering a New Membership Account as the RRA

- Select or hover over the ***Centre Administration*** tab in the RIPPLE Toolbar
- Select ***Register a New Member Account***
- Complete the ***Personal Information***, ***Address Information***, and ***Additional Information*** online forms and attest to the information being accurate
- Note: When ***First Name*** and ***Last Name*** are entered, the ***Account User ID*** will be prefilled with a suggested user ID. You can change the default however the system will only accept unique user IDs. You will use the User ID to login to RIPPLE and other CCTG systems. When a ***Centre*** is selected from the drop down list, the associated form fields in the ***Address Information*** section will be automatically prefilled with the centre's address information. If your address information is different from the centre's update the fields to the correct information.
- Click ***Submit*** to submit the membership account request

3.1.4 Registering a New membership Account as a Member

A membership account can be created without having a CCTG username and password. To do so:

- Open **Toolbox** on the CCTG main webpage and click on **RIPPLE** under Applications
- Select ***Register Member Account*** from the RIPPLE main page Toolbar
- Complete the Personal Information, Address Information, and Additional Information online forms and attest to the information being accurate

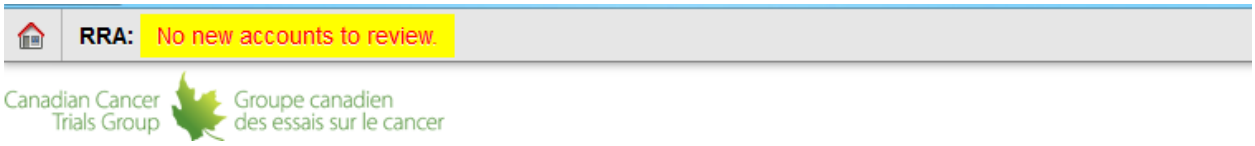
Click ***Submit*** to submit the membership account request

- You will be re-directed to a 'Registration Confirmation' page indicating that your registration was successfully submitted, and that you will be contacted via the email you provided with details about your account once it has been approved

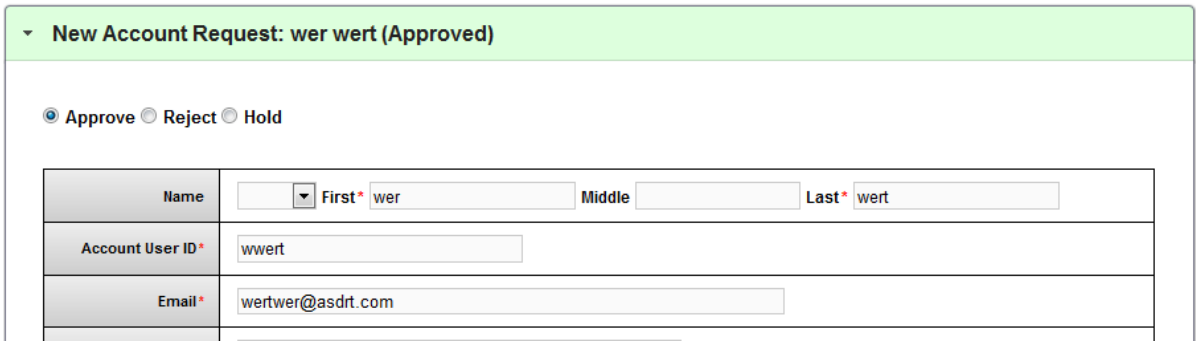
3.1.5 Approving Membership Account Registration

All registrations must be approved by the RRA at the centre they are registered with before any account access will be granted. If the account was registered by the RRA there is no further approval process required. If the individual themselves registered the member account, the RRA will receive an email requesting confirmation that the user is affiliated with their centre once a membership account request has been submitted.

- When logged in to RIPPLE, the RRA will be notified if new accounts are pending review via the top bar on the Main page.



- Click on ***new account(s) to review*** in the top bar
- You will be re-directed to the 'Registration Approval' page, which will list all the new accounts pending approval.
- Click on ***New Account Request***, review the member's information and select ***approve***



- Click ***Submit*** (Note: Once submitted, approved accounts will be sent an email with a link to set their account password. Accounts that are not approved will be notified via email)

3.2 New Member Account Activation

Once a new Member is approved by the RRA at their centre, the Member will receive an email notification to activate their account via the CCTG Password Management Utility. The Member must attest to the CCTG Confidentiality Agreement and initialize their password before their account is activated.

Example email text:

```
Subject: Canadian Cancer Trials Group Member Account Activation

Dear Jane Doe,
```

Welcome to the Canadian Cancer Trials Group Trials Group!

You are receiving this email due to your involvement in CCTG cancer study: [trial code(s)]

Your member user ID is: jdoe

Your registered first name is: Jane

Your registered last name is: Doe

Your registered email is: jdoe@email.com

You must use the Password Management page https://scooby.ctg.queensu.ca/passwords/ to set your member password and activate your member account.

Note: If you require access to the CCTG Medidata Rave EDC system then you will receive an automatic email to set up an EDC account when you are assigned a role to an EDC trial.

Please keep this email for future reference for resetting the password for your member account.

If you do not have access to the necessary areas please refer to our support page http://www.ctg.queensu.ca/help/ for more information.

Thank you for your interest in the CCTG.

This is a system generated email. Please do not respond to this email. Questions and concerns can be sent to the CCTG Help Desk by email at support@ctg.queensu.ca

Once their account is activated the Member can access the members section of the CCTG website as well as RIPPLE. Access to trial/committee websites will be limited based on trials and committee participation.

3.3 Information contained in 'My Member Account'

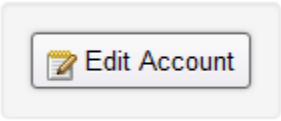
To access 'My Member Account':

- Log in to RIPPLE using the username and password you created.
- Click or hover over ***My Member Account*** in the toolbar. Five options will appear that will allow you to manage your account (***Account Information, Centre Affiliations, My Trials & Roles, Uploads,*** and ***Password Management***):

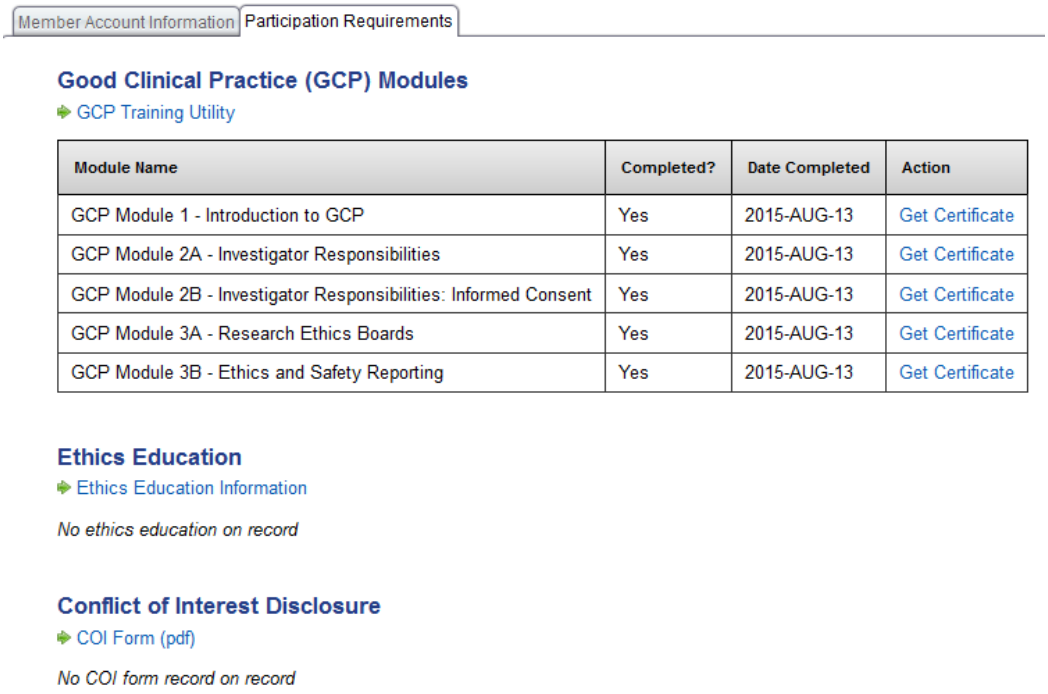
3.3.1 Account Information

Account Information contains two tabs: 'Member Account Information', which opens as the default page and 'Participation Requirements'

Member Account Information displays personal, address, and additional information entered during registration. This page can be edited or updated by clicking the ***Edit Account*** button at the bottom of the page; you can then update fields as applicable and press ***Submit*** to save changes.



Participation Requirements displays information about your required documents, training and credentials. This page contains the record of generic training and credentialing (e.g. GCP and Ethics Education), as well as links to applicable training modules and documents. By clicking on the appropriate links the member will be either redirected to the webpage to complete the required training (e.g. GCP Training Utility or Ethics Education Information) or to access the required document to be completed (e.g. COI Form). Please refer to section 3.3.2 for details on uploading generic training/credentialing documents.



Tracking credentialing in RIPPLE

RIPPLE is linked to other CCTG tools and as such will automatically show the status of your credentialing/training. This includes:

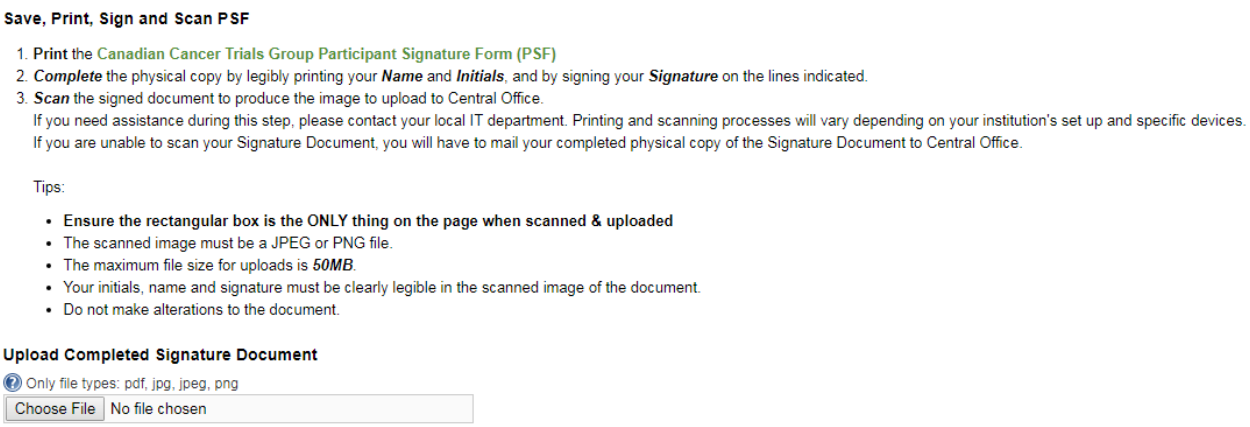
- Investigator CVs
- GCP/Division 5 training
- Ethics Training (NIH Protection of Human Research Participants or CITI Human Subjects Research Course)
- STU (Site Training Utility)

3.3.2 Uploads

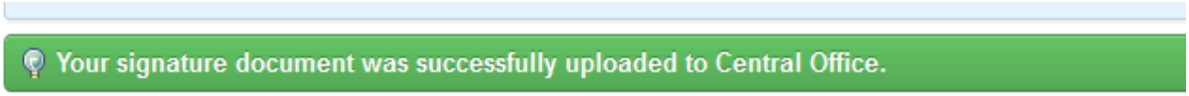
Uploads allows you to upload and submit generic credentialing/training documents to CCTG.

By clicking on ***Uploads*** under ***My Member Account***, you will be taken to the My Upload History page

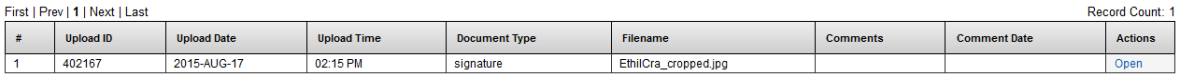
- Select the form to upload
- You will be taken to the upload page for the chosen document (For example the Participant Signature Form)



- Select ***Choose File*** and locate the file (Note: Remember that it must be a JPEG or PNG file)
- When the correct file is chosen select ***Submit***
- If the document was successfully uploaded a message will appear at the top of the page indicating this



- When the upload has finished the uploaded document will appear at the bottom of the page

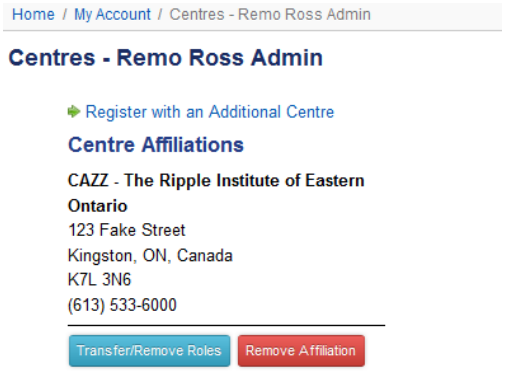


Note: Generic Uploads can be done by the member or by the RRA. Trial specific documents are uploaded/ completed in a different manner. Please refer to section 7.9.2 for details.

3.3.3 Centre Affiliations

The ***Centre Affiliations*** option under ***My Member Account*** allows you to see all the centres in which you are associated through RIPPLE.

All members must be associated with at least one CCTG centre.



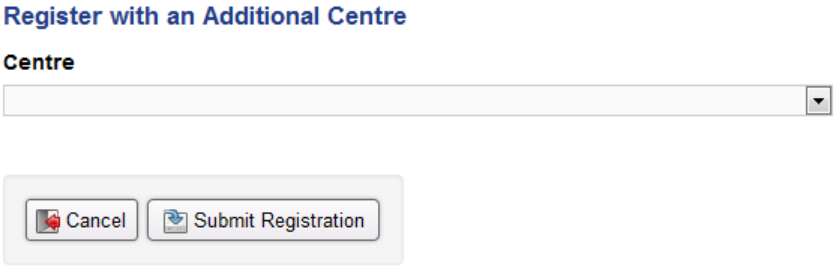
This page also allows a member to register with an additional centre and/ or remove an affiliation with a centre by selecting the appropriate button.

3.3.4 Changing Centres

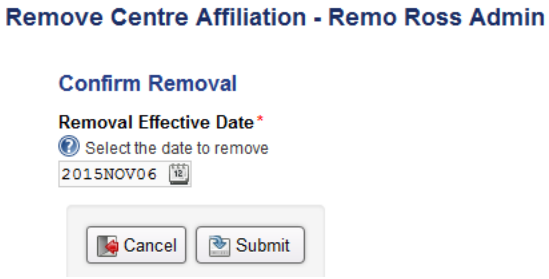
Members can be registered at multiple centres. However, if a member is changing centres, they should first be removed from their current centre before registering with their new centre. To remove a member from a centre please follow the steps below.

- Click ***Register with an Additional Centre***

- Select the appropriate centre from the drop down menu
- Click ***Submit Registration***



- Click ***Remove Affiliation*** for the selected centre
- Select the removal effective date (Removal effective date is the date in which the member will permanently cease membership activities at the centre)
- Click ***Submit***



Note: When either a request to register with an additional centre has been submitted or a removal effective date has been entered into a member's record, the RRA(s) at the affected centre(s) will receive a notification that an addition or removal is pending approval. The RRA at the new centre will need to approve the registration request before member can be activated at the new centre. The RRA at the previous centre must approve the removal from their centre as well. Removal approvals are processed in the same way a registration request is approved.

A member can be affiliated with more than one CCTG member centre. In this case, each centre will be listed in the Centre Affiliations page.

3.3.4.1 Leaving a Centre

When an RRA enters the removal effective date in a members account, a requested stop date is automatically populated for all trials in RIPPLE for which the member has an "active" role. A notification is sent to each applicable QI to approve this date.

Note: the auto- populated stop date can be overwritten if needed for each role. The 'Transfer/Remove Roles' utility can also be used to reassign the participants. This utility is found under the Centre Affiliation tab which you will see when a person is selected from the list of Centre Members in RIPPLE. Please refer to section 7.10.2 for details on this process. If the trial is not in RIPPLE, please ensure a paper Participants List Change Form is submitted for each applicable trial. A list of all trials in which the member is participating is available in RIPPLE under the Center Administration tab > Centre Members tab > selecting the member. Refer to section 5.1 for further details.

3.3.5 Password Management

The ***Password Management*** option under ***My Member Account*** allows you to modify your password.

- Log into RIPPLE
- Select 'My Member Account'
- Select 'Password Management'

Using this utility you can change, reset or test your account password. You can also recover access to your EDC account.

The Password Management Utility can only be assessed by the Member.

3.3.6 My Trials & Roles

The ***My Trials & Roles*** option under ***My Member Account*** allows you to view your current trial related roles.

- Log into RIPPLE
- Select ‘My Member Account’
- Select ‘My Trials & Roles’

3.3.7 Personnel authorized to access to ‘My Member Account’ information

Account information can be viewed and updated by the member, the RRAs at the member’s centre and CCTG Central Office.

Password information can only be accessed by the Member. Current passwords cannot be viewed, but can be initialized or reset.

4 PARTICIPANT SIGNATURE FORM

4.1 Participant Signature Form (PSF)

To ensure compliance with GCP (4.1.3, 8.3.24) and Canadian regulations (C.05.012), CCTG requires a Participant Signature Form (PSF) to be submitted for all site research personnel. These forms will be used to generate Trial Signature Reports (TSR) showing the signatures and initials of all persons authorized by the Qualified Investigator to perform significant trial related duties. TSRs will be used to verify or authenticate trial related documentation as applicable. PSFs are required for any participant that is on a Trial PL in RIPPLE. Any member who was active on a trial in RIPPLE for any period of time must submit a PSF.

4.2 PSF submission process

PSFs must be dated, signed and initialed (must be hand written), and then submitted using the ***Upload*** feature found under the ***My Member Account*** tab in RIPPLE. The file must be in an image format, jpeg is preferred. The system will not accept a PDF file. When the ***Submit Signature Document*** option is selected you will be taken to a new page where the PSF can be downloaded. Detailed instructions are provided on this page as well. Please refer to section 3.3.2.

The PSF can be uploaded by the member or by any of the RRAs at a centre.

For new members, the PSF should be submitted after the member's registration is approved by the RRA. An updated PSF should also be submitted in the event that the member's signature or initials change (e.g. a change in last name).

If the member is not active on any trials that are managed via RIPPLE there will be no action required. Members who are active on trials in RIPPLE are required to have a PSF and should submit a PSF as soon as possible. Trial participation/access can be impacted by the status of the PSF as PSFs are an activation requirement for all roles assigned to RIPPLE Trial Participants Lists.

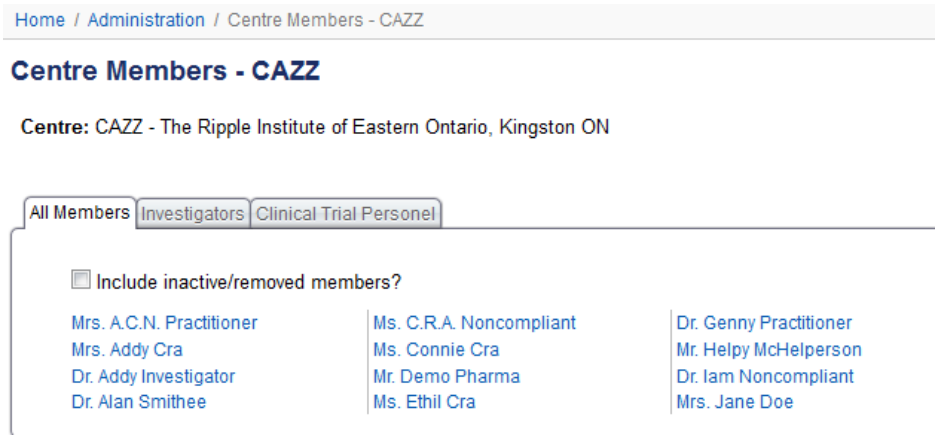
If a PSF cannot be obtained for a valid reason, please contact RIPPLE@ctg.queensu.ca for guidance. Additional documentation (e.g., note to file) may be requested.

5 MEMBER ACCOUNT SUMMARIES IN RIPPLE

RIPPLE is capable of producing various centre level summary reports which allow for a fast overview of member participation and credentialing status.

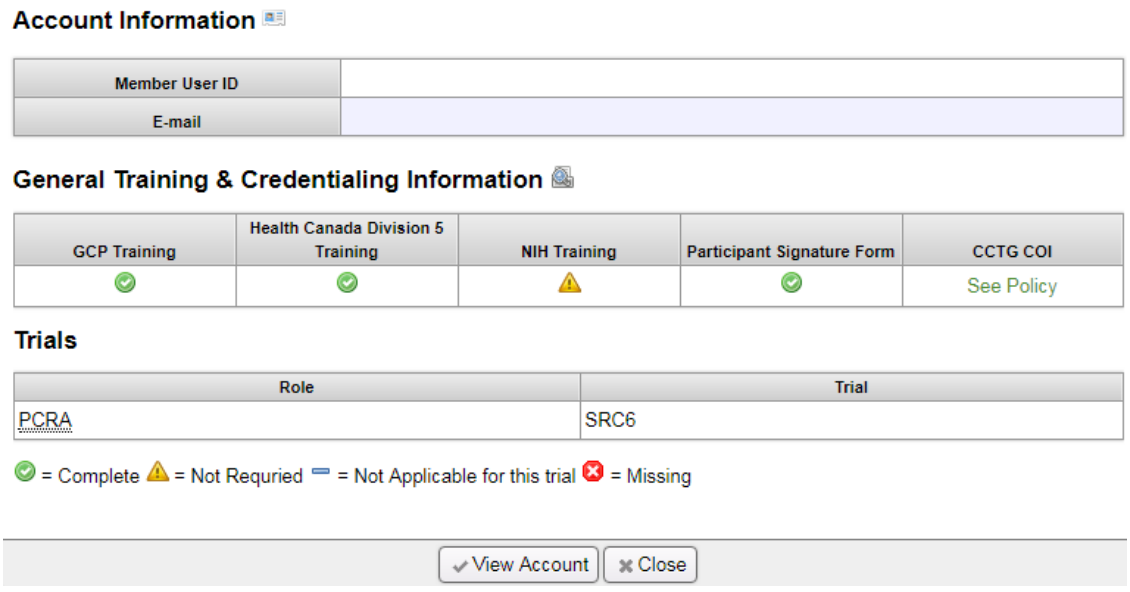
5.1 Centre Member Summaries

- Click or hover over the ***Centre Administration*** tab in RIPPLE toolbar, and select ***Centre Members***
- A listing of all members at your centre will appear (Note: Can also select to include inactive/removed members using the checkbox above the members list)



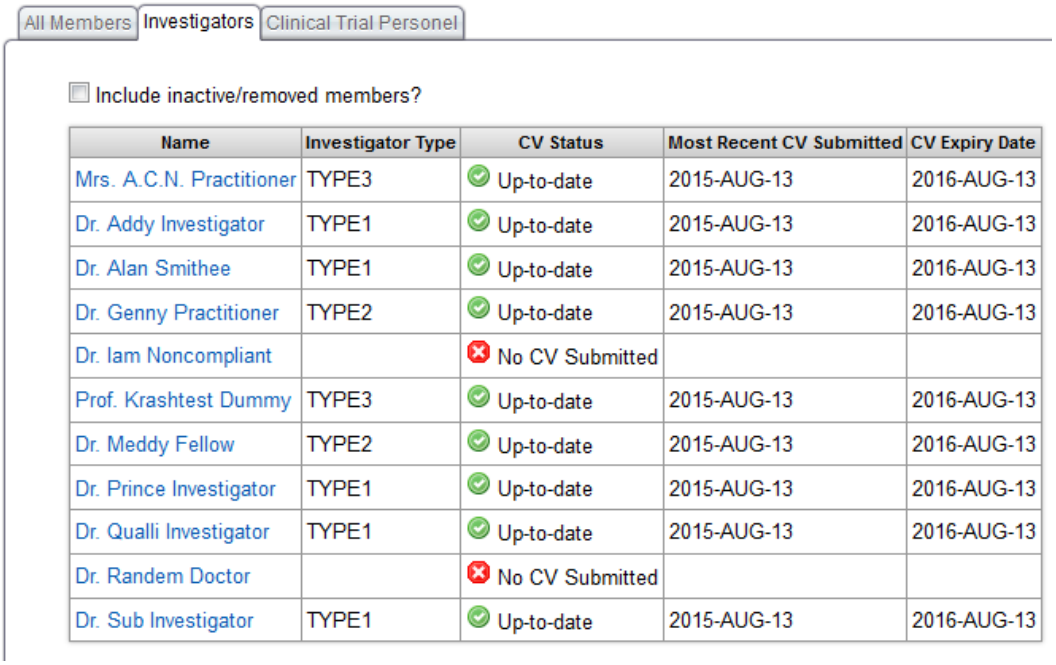
5.1.1 All Members

Clicking on an individual member will show their account information, which includes member ID, email, generic training and credentialing information and trial roles (only includes trials that are in RIPPLE). This report will also indicate if a member has incomplete or outstanding credentials.



5.1.2 **Investigators**

This tab lists all the investigators at the centre and provides a summary of Investigator Type and current CV status, with submission and expiry dates.



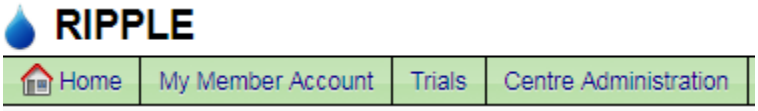
Name	Investigator Type	CV Status	Most Recent CV Submitted	CV Expiry Date
Mrs. A.C.N. Practitioner	TYPE3	Up-to-date	2015-AUG-13	2016-AUG-13
Dr. Addy Investigator	TYPE1	Up-to-date	2015-AUG-13	2016-AUG-13
Dr. Alan Smithee	TYPE1	Up-to-date	2015-AUG-13	2016-AUG-13
Dr. Genny Practitioner	TYPE2	Up-to-date	2015-AUG-13	2016-AUG-13
Dr. Iam Noncompliant		No CV Submitted		
Prof. Krashtest Dummy	TYPE3	Up-to-date	2015-AUG-13	2016-AUG-13
Dr. Meddy Fellow	TYPE2	Up-to-date	2015-AUG-13	2016-AUG-13
Dr. Prince Investigator	TYPE1	Up-to-date	2015-AUG-13	2016-AUG-13
Dr. Qualli Investigator	TYPE1	Up-to-date	2015-AUG-13	2016-AUG-13
Dr. Randem Doctor		No CV Submitted		
Dr. Sub Investigator	TYPE1	Up-to-date	2015-AUG-13	2016-AUG-13

6 RIPPLE ROLES

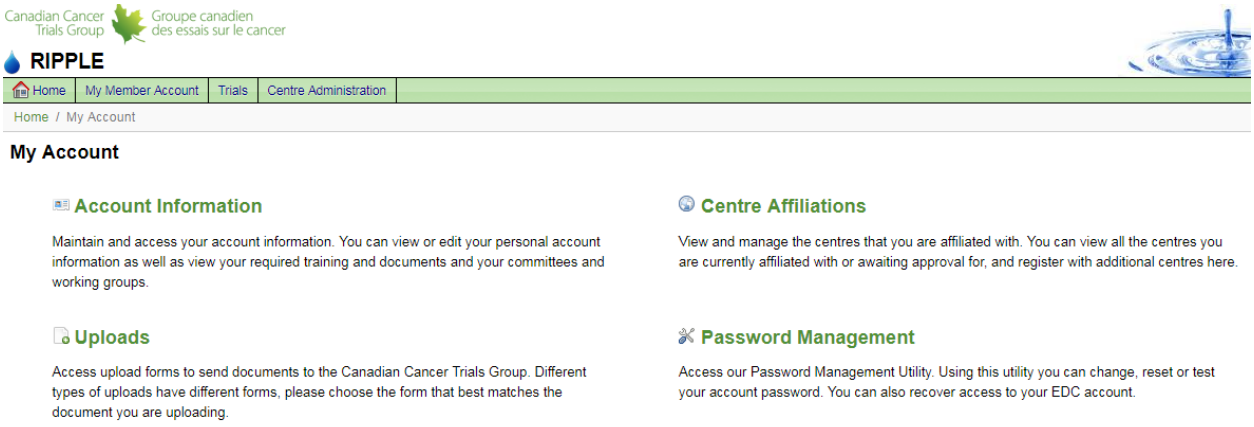
6.1 Assigning RIPPLE roles

RIPPLE roles include the Remote Roster Administrator (RRA), the Participants List Administrator (PLA) and the Participants List Delegate (PLD). Both the PLA and the PLD are assigned by centre staff within RIPPLE, while the RRA is assigned via a form sent to central office. These roles can administer the trial Participants Lists, but they do not have trial specific duties (which are assigned on the trial Participants Lists).

Anyone who is assigned as an RRA, PLA or PLD can access the centre administration page to assign RIPPLE specific roles. To do so click on ***Centre Administration*** in the top toolbar.



Please see the sample Centre Administration page below. Note that not all Members will have the same Centre Administration page as it varies for RRAs, QIs, PLDs and PLAs.



To assign a RIPPLE role click on ***Assign RIPPLE Roles.*** The ***RIPPLE Roles*** table can also be viewed by selecting ***RIPPLE roles*** directly from the ***Centre Administration*** toolbar. To assign specific roles please follow the steps in the sections 6.2 and 6.3 of this manual.

Please note that the PLA or PLD can only assign RIPPLE roles for trials to which they are assigned, unlike the RRA who can assign RIPPLE roles for all trials in which the centre is participating.

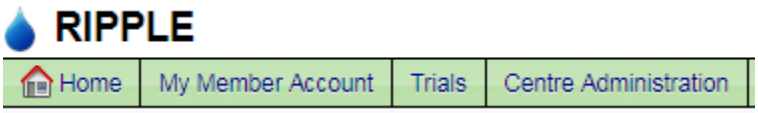
6.2 Participants List Administrator

PLAs are Members designated by the centre to create and administer the Trial PL in RIPPLE. PLAs have permission to create and edit Participants Lists for specific trials. There is no limitation on the maximum number of PLAs per trial at a centre. PLAs can be assigned to ALL trials or to specific trials (as applicable for the centre).

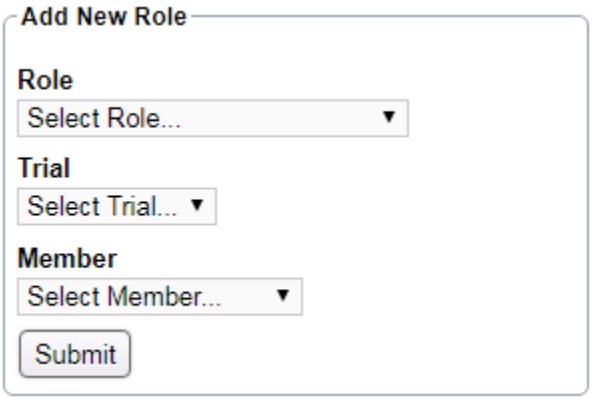
The assignment of PLAs is done within RIPPLE by the centre RRA, PLD, QI or another PLA on the same trial and can be updated locally as needed.

6.2.1 Adding the PLA

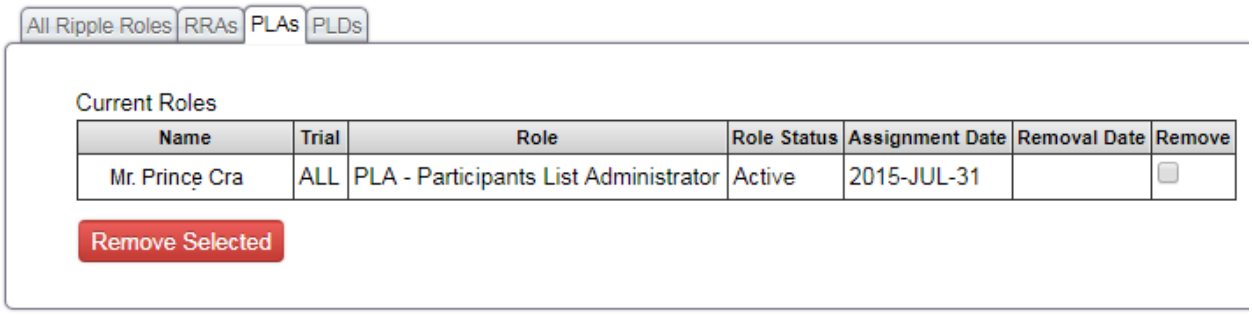
- From the ***Centre Administration*** area on the top tool bar (RRAs, PLAs, PLDs will have this option on the RIPPLE main page), select ***RIPPLE roles*** from the drop down menu



- Select ***Participants List Administrator*** from the Role drop down list
- Select a specific trial from the drop down list if the PLA is only going to be assigned to one trial or select ALL if the PLA is going to be assigned all trials at your centre
    - If ALL is selected then the PLA will automatically be assigned to all trials in RIPPLE that the centre is currently participating on as well as all future trials that are added
- Select the name of the PLA from the drop down list which includes all active Members at the centre



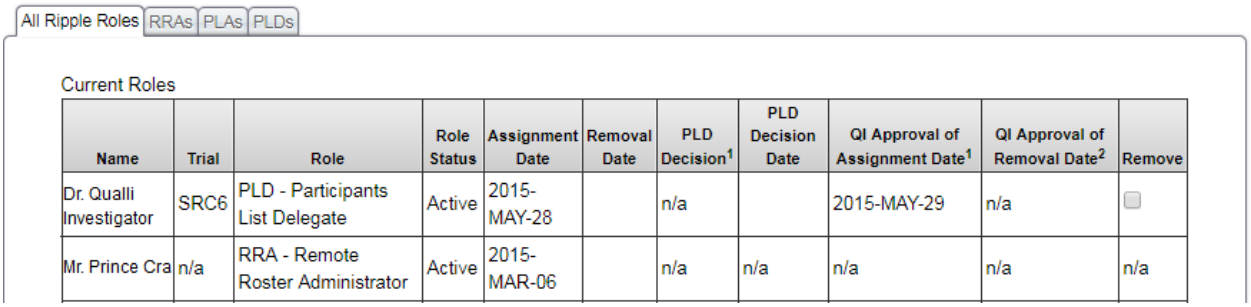
- Select ***Submit***
- Confirm the individual has been assigned the PLA role for the appropriate trial(s) under the PLA tab in the RIPPLE Roles table on the same page



- QI approval is not required for assignment of the PLA because changes made by the PLA will still require QI (or PLD) approval
- The PLA permissions are effective the next time the PLA logs in to RIPPLE

6.2.2 Removing the PLA

- On the ***RIPPLE Roles page***, select the ***All RIPPLE Roles*** tab and then select a role/individual to be removed using the checkbox in the remove column in the Current Roles table



Name	Trial	Role	Role Status	Assignment Date	Removal Date	PLD Decision[1]	PLD Decision Date	QI Approval of Assignment Date[1]	QI Approval of Removal Date[2]	Remove
Dr. Qualli Investigator	SRC6	PLD - Participants List Delegate	Active	2015-MAY-28		n/a		2015-MAY-29	n/a	☐
Mr. Prince Cra	n/a	RRA - Remote Roster Administrator	Active	2015-MAR-06		n/a	n/a	n/a	n/a	n/a

- Select ***Remove Selected*** at the bottom of the page

- Date removed = date removal completed in RIPPLE

Mr. Prince Cra	I226	PLA - Participants List Administrator	Removed	2017-SEP-11	2018-JAN-04	n/a	n/a	n/a	n/a	n/a

- QI approval is not required for removal of a PLA

6.3 Participants List Delegate

Where permissible by local SOPs, the Qualified Investigator (QI) can assign the task of approving the delegation of trial related duties in RIPPLE (i.e., the trial Participants Lists) to an appropriately qualified individual – the PLD**.**

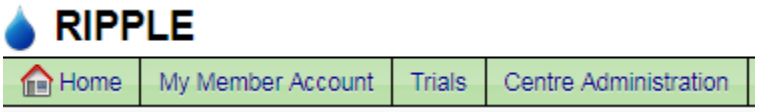
The PLD role is **optional** and is only applicable to trials in RIPPLE. There can only be 1 PLD per trial at each centre. A PLD can modify PLs and CAN approve all PL changes, whereas an RRA and PLA can create/modify PLs but CANNOT approve PL changes.

6.3.1 Becoming a PLD

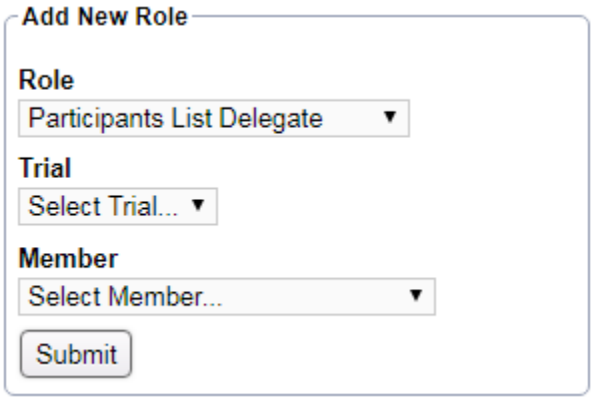
Determining who is an appropriately qualified individual is at the discretion of the QI and should be in accordance with local SOP(s). The QI remains ultimately responsible for the delegation of trial related duties and should therefore ensure the PLD role is assigned to personnel who understand the roles and responsibilities that they are delegating. The task of approving the delegation of trial related duties in RIPPLE must be supported by local SOPs and centres must follow their local policy for trial delegation and approval. The PLD must have an active CCTG membership account. Until the PLD role is accepted by the delegate and approved by the QI, the QI is responsible for all trial delegation.

6.3.2 Adding the PLD

- From the ***Centre Administration*** area on the top tool bar (RRAs, PLAs, PLDs, and QIs will have this option on the RIPPLE main page), select ***RIPPLE Roles*** from the drop down menu



- Select ***Participants List Delegate*** from the Role drop down list
- Select ***a specific trial*** from the drop down list to which the PLD is going to be assigned (please note you cannot select "all" for the PLD)
- Select the ***name of the PLD*** from the drop down list which includes all active **Members** at your centre



- Select ***Submit***

6.3.3 Accepting or Rejecting the PLD assignment

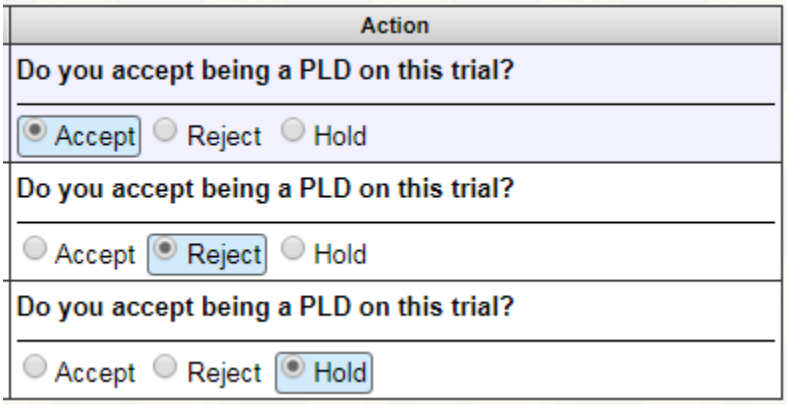
The participant who was assigned the PLD role must sign in to their RIPPLE account to accept or reject the PLD assignment. If the participant was assigned the PLD role for more than one trial then they will have to accept or reject this assignment for each trial separately.

- The pending PLD may sign in to RIPPLE at any time to approve the PLD assignment by selecting ***PLD Decision Required*** at the top left

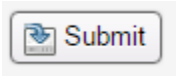
- The Batch Approvals page appears with a list of pending PLD decisions.

Centre	Trial	QI Approval?	Action
CA ZZ	CEC5	Pending	Do you accept being a PLD on this trial? Accept Reject Hold

- To accept the PLD assignment select ***Accept***, to reject the PLD assignment select ***Reject***, to neither Accept or Reject the assignment select ***Hold***



- After selecting an option for each PLD assignment select ***Submit***



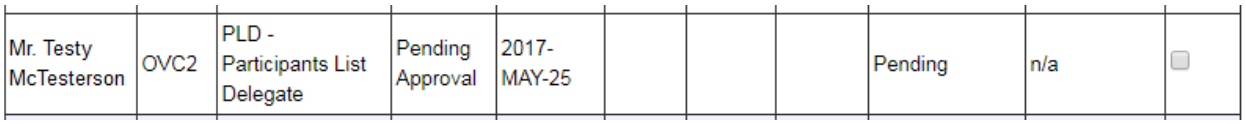
- A notification will appear indicating ***PLD Decisions: Accepted X, Rejected X, X on Hold***

- For the trials for which the PLD assignment was accepted the participant can immediately start performing PLD duties

6.3.4 QI Approval of PLD

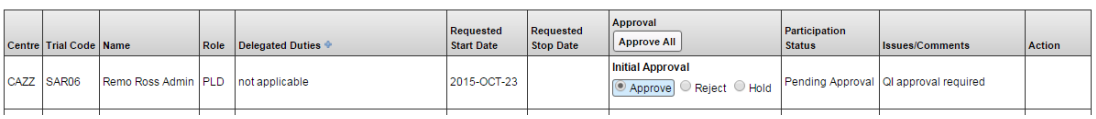
- The QI will receive a notification that there is a pending PLD change requiring approval, along with notification of pending PL changes. The QI may sign in to RIPPLE at any time to approve the PLD.

- In the RIPPLE roles table the ***Role Status*** column will show ***Pending Approval*** until the change has been approved.



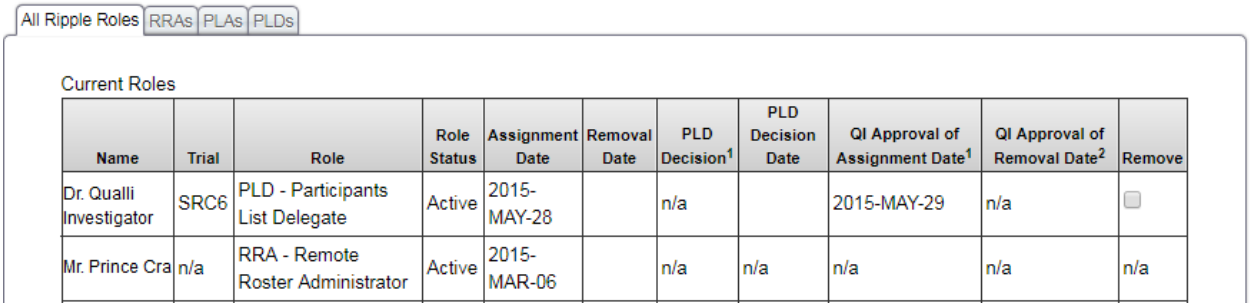
Mr. Testy McTesterson	OVC2	PLD - Participants List Delegate	Pending Approval	2017-MAY-25				Pending	n/a	

- The PLD is not able to approve/delegate roles or maintain the Participants List until the QI has approved the PLD role. The PLD can however be approved by a pending QI as long as the QI has met all training and credentialing requirements.
    - Please note that the initial trial Participants List (with the minimum mandatory roles entered) must be created in RIPPLE prior to a QI being able to approve a PLD



Centre	Trial Code	Name	Role	Delegated Duties	Requested Start Date	Requested Stop Date	Approval (Approve All)	Participation Status	Issues/Comments	Action
CAZZ	SAR06	Remo Ross Admin	PLD	not applicable	2015-OCT-23		Initial Approval: Approve Reject Hold	Pending Approval	QI approval required	

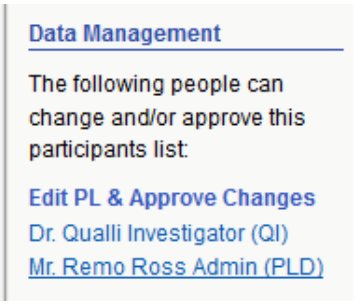
- The PLD will appear on the Current Roles table on the RIPPLE Roles page


All Ripple Roles | RRAs | PLAs | PLDs

Current Roles

Name	Trial	Role	Role Status	Assignment Date	Removal Date	PLD Decision[1]	PLD Decision Date	QI Approval of Assignment Date[1]	QI Approval of Removal Date[2]	Remove
Dr. Qualli Investigator	SRC6	PLD - Participants List Delegate	Active	2015-MAY-28		n/a		2015-MAY-29	n/a	☐
Mr. Prince Cra	n/a	RRA - Remote Roster Administrator	Active	2015-MAR-06		n/a	n/a	n/a	n/a	n/a

- As well as on the Trial PL page for each relevant trial and on the Participants List (Detailed) Report.


Data Management

The following people can change and/or approve this participants list:

Edit PL & Approve Changes

Dr. Qualli Investigator (QI)

Mr. Remo Ross Admin (PLD)

6.3.5 **Removal of the PLD:**

- On the same ***RIPPLE Roles*** page, the RRA can select the role/individual to be removed by selecting the PLD tab and then the checkbox in the ***Remove*** column

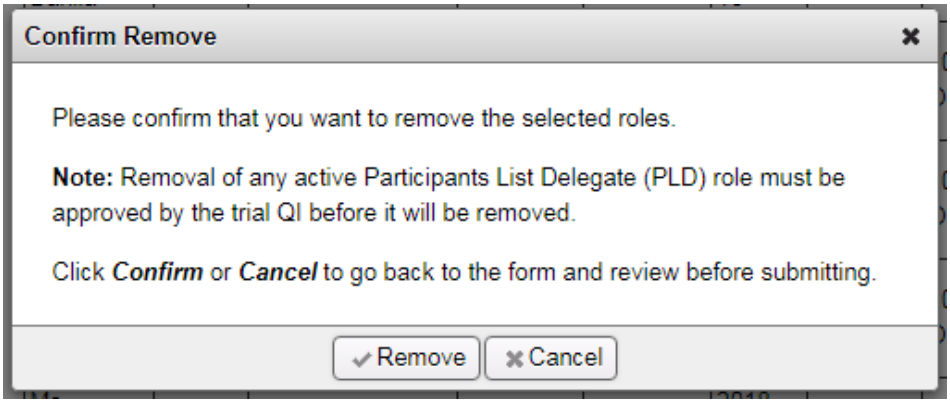
Current Roles

Name	Trial	Role	Role Status	Assignment Date	Removal Date	PLD Decision[1]	PLD Decision Date	QI Approval of Assignment Date[1]	QI Approval of Removal Date[2]	Remove
Mr. Prince Cra	BR34	PLA - Participants List Administrator	Active	2018-SEP-26		n/a	n/a	n/a	n/a	☐
Mr. Prince Cra	I227	PLA - Participants List Administrator	Active	2018-SEP-26		n/a	n/a	n/a	n/a	☐
Mr. Testy McTesterson	MA32	PLD - Participants List Delegate	Active	2017-SEP-05		n/a		2017-SEP-11	n/a	☑

- Select ***Remove Selected***


Remove Selected

- A notification will pop up confirming that the PLD is to be removed. Select ***Remove***



- Removal requires QI approval. The QI will receive a notification that this removal is pending approval as part of the PL pending changes email.

Centre	Trial Code	Name	Role	Delegated Duties	Requested Start Date	Requested Stop Date	Approval Approve All	Participation Status	Issues/Comments	Action
CAZZ	SAR06	Remo Ross Admin	PLD	not applicable	2015-OCT-23	2015-OCT-23	Initial Approval *2015-OCT-23* Stop Approval Acknowledge Hold		QI approval required	

- The ***Requested Stop Date*** is the date that the request is entered in RIPPLE and not the date of QI approval.

6.3.6 The PLD and RIPPLE Notifications

The QI will be notified via email when there are PLD additions or removals that require approval. If there is no PLD then the QI will receive the email notifications for all outstanding PL approvals for the trial.

Once a PLD is approved, email notifications for outstanding PL approvals will go to the PLD instead of to the QI for that trial. The QI can also be added to notifications if preferred locally (please refer to Notifications section 7.12). When a PLD is removed the QI is informed that they are again responsible for PL approvals for that trial.

For step-by-step instructions on QI/PLD approvals please refer to section 5.6 of this manual.

QIs can ALWAYS view the complete Participants Lists at any time in RIPPLE and complete any approvals even if there is an active PLD!

6.4 Viewing RIPPLE Roles for Your Centre/Trial

There are multiple ways to view the various roles at a centre and whom they are assigned to

1. On the RIPPLE home page the Data Management tables list QIs, PLDs and PLAs at a centre by trial

Qualified Investigator

Approve & Modify Participants Lists	
Name	**Trials**
Qualli Investigator	LY17, MA36, SAR06, SCL32

PL Delegate

Approve & Modify Participants Lists	
Name	**Trials**
Remo Ross Admin	SCL32

PL Administrator

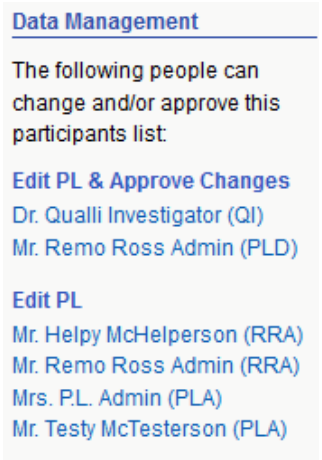
Create & Modify Participants Lists	
Name	**Trials**
Addy Cra	CRC7
P.L. Admin	ALL
Testy McTesterson	ALL

2. From ***Centre Administration*** select ***RIPPLE roles***
   - The ***Current Roles*** table lists all RRAs, PLAs, and PLDs. This table is only accessible by RRAs, PLDs, PLAs and Qis
   - There are 4 tabs that can be selected on this table to make viewing roles easier: All RIPPLE Roles, RRAs, PLAs and PLDs

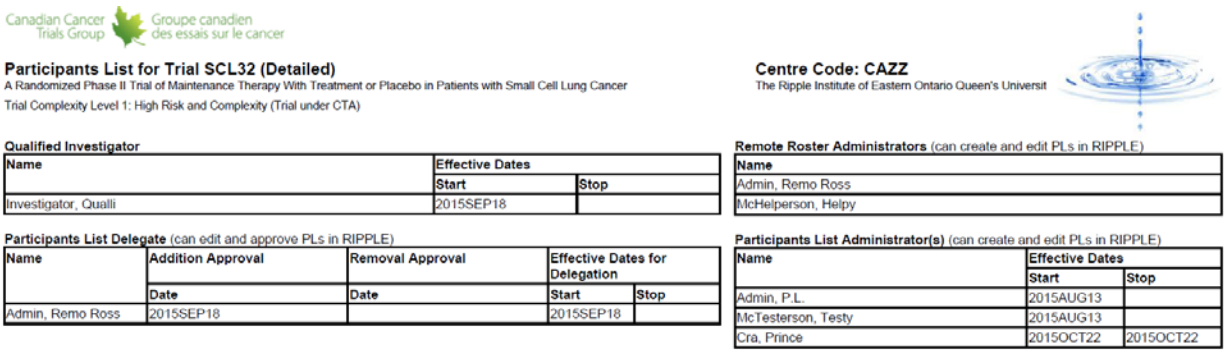
Current Roles

Name	Trial	Role	Role Status	Assignment Date	Removal Date	PLD Decision[1]	PLD Decision Date	QI Approval of Assignment Date[1]	QI Approval of Removal Date[2]	Remove
Mr. Prince Cra	BR34	PLA - Participants List Administrator	Active	2018-SEP-26		n/a	n/a	n/a	n/a	☐
Mr. Prince Cra	I227	PLA - Participants List Administrator	Active	2018-SEP-26		n/a	n/a	n/a	n/a	☐
Mr. Testy McTesterson	MA32	PLD - Participants List Delegate	Active	2017-SEP-05		n/a		2017-SEP-11	n/a	☐
Mr. Testy McTesterson	MA32D	PLD - Participants List Delegate	Active	2017-SEP-05		n/a		2017-SEP-25	n/a	☐
Mr. Testy McTesterson	PRC4	PLD - Participants List Delegate	Active	2017-SEP-05		n/a		2017-SEP-06	n/a	☐
Mr. Helpy McHelperson	n/a	RRA - Remote Roster Administrator	Active	2014-DEC-11		n/a	n/a	n/a	n/a	n/a

3. On the right hand side of any ***Trial PL page*** under ***Data Management*** there is a list of individuals that can edit and approve PLs (QI & PLD) and who can edit PLs (RRAs & PLAs) for that trial



4. QIs, RRAs, and applicable QIs, PLAs and PLDs will appear at the top of the first page on the ***Participants List Report (Detailed)***



Canadian Cancer Trials Group / Groupe canadien des essais sur le cancer

Participants List for Trial SCL32 (Detailed)

A Randomized Phase II Trial of Maintenance Therapy With Treatment or Placebo in Patients with Small Cell Lung Cancer

Trial Complexity Level 1: High Risk and Complexity (Trial under CTA)

Centre Code: CAZZ

The Ripple Institute of Eastern Ontario Queen's Universit

Qualified Investigator

Name	Effective Dates	
	Start	Stop
Investigator, Qualli	2015SEP18	

Remote Roster Administrators (can create and edit PLs in RIPPLE)

Name
Admin, Remo Ross
McHelperson, Helpy

Participants List Delegate (can edit and approve PLs in RIPPLE)

Name	Addition Approval	Removal Approval	Effective Dates for Delegation	
	Date	Date	Start	Stop
Admin, Remo Ross	2015SEP18		2015SEP18	

Participants List Administrator(s) (can create and edit PLs in RIPPLE)

Name	Effective Dates	
	Start	Stop
Admin, P.L.	2015AUG13	
McTesterson, Testy	2015AUG13	
Cra, Prince	2015OCT22	2015OCT22

7 PARTICIPANTS LISTS

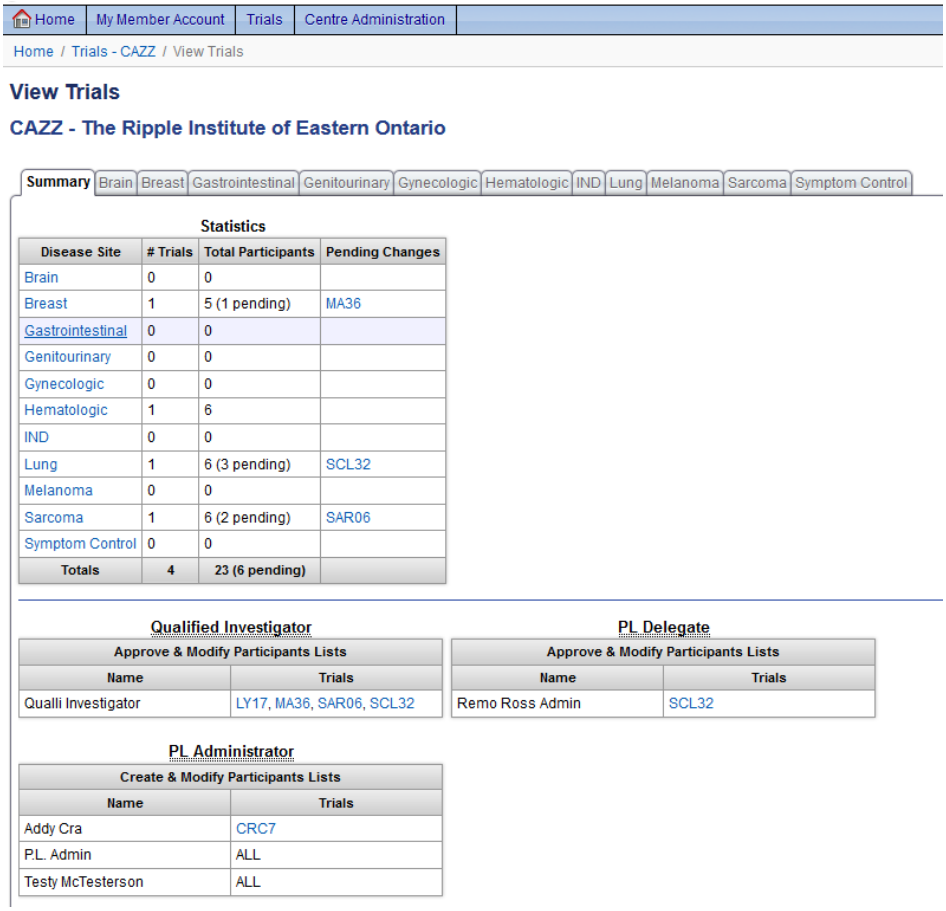
7.1 Participants List Permissions by Role

Role	Create a PL?	Modify a PL?	Approve a PL?
RRA	Yes	Yes	No
PLA	Yes	Yes	No
PLD	No	Yes	Yes
QI	No	Yes	Yes

7.2 How to Access a Trial Participants List

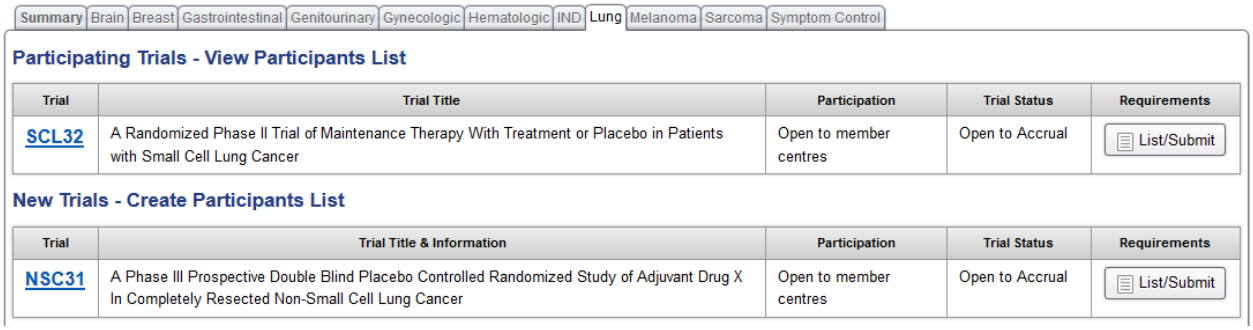
After signing in to RIPPLE a participant will be taken to their centre homepage. On the homepage there are tables and tabs that give a quick overview of the trials at the centre. The following tables are under the ***Home Page*** tab:

- **Statistics-** This table shows all of the trials a centre is participating on. The number of trials in each disease site, the total participants for each disease site and trials with pending changes are all viewable here.
- **RIPPLE Roles tables-** These tables list QIs, PLDs and PLAs at a centre and which trials they are participating on.



The tabs on the homepage cover all disease sites. Clicking on a disease site will show all the trials under that portfolio that are using RIPPLE to manage trial PLs. There are 2 tables under each portfolio:

- **Participating Trials - View PL**: This lists the trials that a centre is participating on for a specific disease site. The Trial Code, Trial Title, Participation status (for example if the trial is open to all member centres), and Trial Status (for example if the trial is open or closed to accrual) can be seen here. Training and credentialing requirements for a particular trial are also viewable here.
- **New Trials – Create PL**: This table shows the Trial ID, the Trial Title, Participation status, Trial Status, and Requirements



On both of these tables clicking on the ***Trial Code*** will go directly to the trial webpage.

Clicking on ***List/Submit*** under ***Requirements*** will go to the table that lists all of the training and credentialing requirements for the various roles on a particular trial.

Trial Participation Requirements - SCL32

Trial Complexity Level: 1

CAZZ - The Ripple Institute of Eastern Ontario

Standard Training & Credentialing Requirements

Refer to https://www.ctg.queensu.ca/trials/generic_forms/PL_PLCF/pl_plcf_requirements.html.

Trial Requirements

Requirements / Roles	QI	PCRA	ECRA	PPHARM	SI	ACRA	PHARM	PTECH	Duty 1	Duty 3
GCP Training	!	!	!	!	!	!	!	!		
Health Canada Division 5 Training	!	!	!	!	!	!	!	!		
NIH Training	!				!					
Site Training Utility	!									
Curriculum Vitae	!				!					
Investigator Type Requirement	Type 1 Investigator								Type 1 Investigator	Type 1 Investigator
QIU Form	!									
Study Acknowledgement/Disclosure	!									

! = Required, click to submit/upload

Complexity Description

Level 1: High Risk and Complexity; Trials that require sub-specialization within the field of oncology, including experience in the conduct of clinical research evaluating highly complex interventions.

Role Descriptions

QI = Qualified Investigator
PCRA = Principal Clinical Research Associate
ECRA = Ethics Clinical Research Associate
PPHARM = Principal Pharmacist
SI = Sub-Investigator
ACRA = Additional Clinical Research Associate
PHARM = Pharmacist
PTECH = Pharmacy Technician

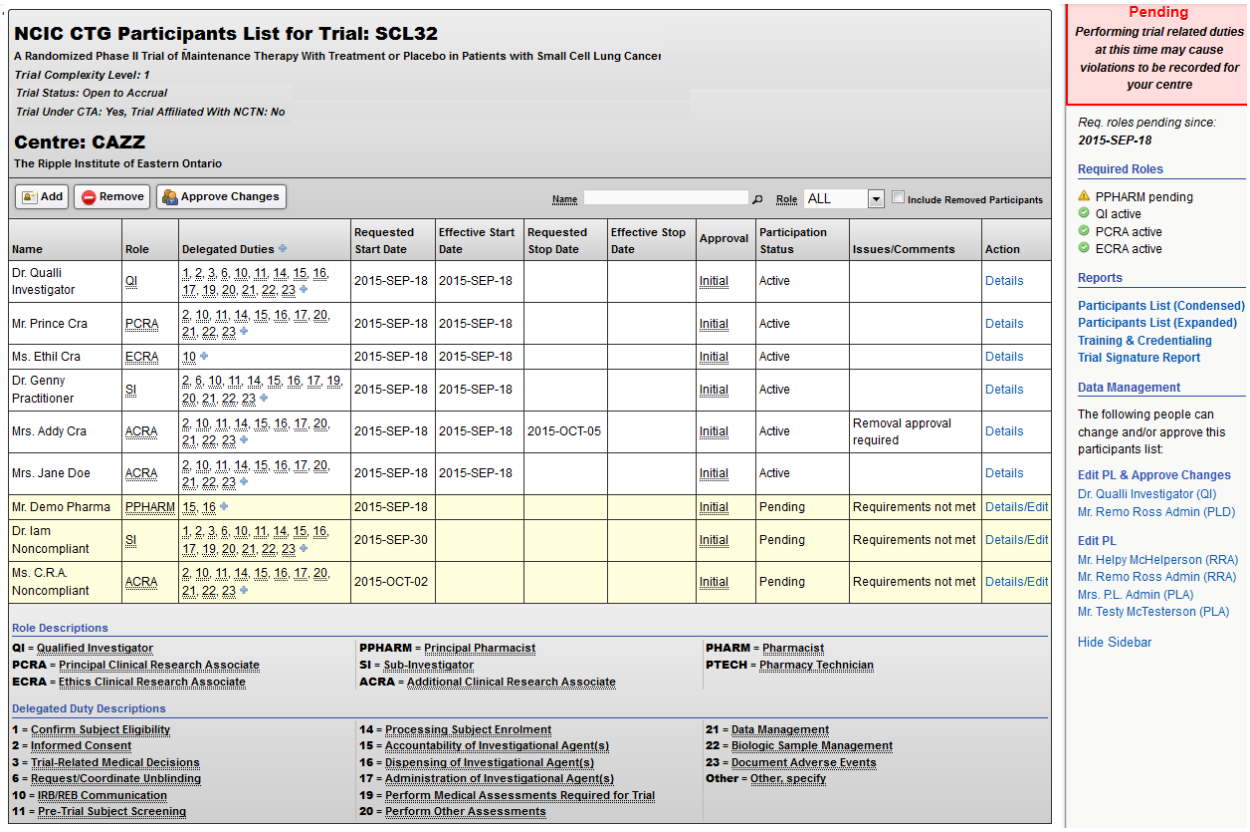
Duty Descriptions

1 = Confirm Subject Eligibility
3 = Trial-Related Medical Decisions

All training and credentialing requirements are listed in the left hand column. Across the top row are the various roles that are on the trial PL. Requirements that are mandatory for a Role will be indicated with a ***required icon***. For example, in the table above a CV is required for the QI and SI but not for other roles while GCP training is required for all roles.

The requirements that are listed are satisfied either by uploading the specific document or by completing training in an alternate system (for example, GCP or STU training) that is checked by RIPPLE. Clicking on the required icon allows a participant to upload any outstanding documents or complete outstanding training (Please refer to section 7.9 - Credentialing and Training for detailed instructions).

Note that CVs will require approval by CCTG before they are effective in RIPPLE.



NCIC CTG Participants List for Trial: SCL32

A Randomized Phase II Trial of Maintenance Therapy With Treatment or Placebo in Patients with Small Cell Lung Cancer

Trial Complexity Level: 1

Trial Status: Open to Accrual

Trial Under CTA: Yes, Trial Affiliated With NCTN: No

Centre: CAZZ

The Ripple Institute of Eastern Ontario

Add | Remove | Approve Changes | Name | Role ALL | Include Removed Participants

Name	Role	Delegated Duties	Requested Start Date	Effective Start Date	Requested Stop Date	Effective Stop Date	Approval	Participation Status	Issues/Comments	Action
Dr. Qualli Investigator	QI	1, 2, 3, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23	2015-SEP-18	2015-SEP-18			Initial	Active		Details
Mr. Prince Cra	PCRA	2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23	2015-SEP-18	2015-SEP-18			Initial	Active		Details
Ms. Ethil Cra	ECRA	10	2015-SEP-18	2015-SEP-18			Initial	Active		Details
Dr. Genny Practitioner	SI	2, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23	2015-SEP-18	2015-SEP-18			Initial	Active		Details
Mrs. Addy Cra	ACRA	2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23	2015-SEP-18	2015-SEP-18	2015-OCT-05		Initial	Active	Removal approval required	Details
Mrs. Jane Doe	ACRA	2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23	2015-SEP-18	2015-SEP-18			Initial	Active		Details
Mr. Demo Pharma	PPHARM	15, 16	2015-SEP-18				Initial	Pending	Requirements not met	Details/Edit
Dr. Iam Noncompliant	SI	1, 2, 3, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23	2015-SEP-30				Initial	Pending	Requirements not met	Details/Edit
Ms. C.R.A. Noncompliant	ACRA	2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23	2015-OCT-02				Initial	Pending	Requirements not met	Details/Edit

Role Descriptions

QI = Qualified Investigator
PCRA = Principal Clinical Research Associate
ECRA = Ethics Clinical Research Associate
PPHARM = Principal Pharmacist
SI = Sub-Investigator
ACRA = Additional Clinical Research Associate
PHARM = Pharmacist
PTECH = Pharmacy Technician

Delegated Duty Descriptions

1 = Confirm Subject Eligibility
2 = Informed Consent
3 = Trial-Related Medical Decisions
6 = Request/Coordinate Unblinding
10 = IRB/REB Communication
11 = Pre-Trial Subject Screening
14 = Processing Subject Enrolment
15 = Accountability of Investigational Agent(s)
16 = Dispensing of Investigational Agent(s)
17 = Administration of Investigational Agent(s)
19 = Perform Medical Assessments Required for Trial
20 = Perform Other Assessments
21 = Data Management
22 = Biologic Sample Management
23 = Document Adverse Events
Other = Other, specify

Pending

Performing trial related duties at this time may cause violations to be recorded for your centre

Req. roles pending since: ***2015-SEP-18***

Required Roles

- PPHARM pending
- QI active
- PCRA active
- ECRA active

Reports

Participants List (Condensed)
Participants List (Expanded)
Training & Credentialing
Trial Signature Report

Data Management

The following people can change and/or approve this participants list:

Edit PL & Approve Changes
Dr. Qualli Investigator (QI)
Mr. Remo Ross Admin (PLD)

Edit PL
Mr. Helpy McHelperson (RRA)
Mr. Remo Ross Admin (RRA)
Mrs. P.L. Admin (PLA)
Mr. Testy McTesterson (PLA)

Hide Sidebar

Non trial specific Member and PL information that was previously submitted to CCTG on paper Participants Lists for trials using RIPPLE has been moved in to RIPPLE, and does not need to be re-entered. You will be able to see all of this information by viewing the existing PL.

7.3 Start and Stop Dates

Start Dates

Requested start date = Date the centre enters as the date that a participant is planning to start performing a role and the duties associated with it

Date requirements met = Date all of the credentialing/training requirements are met for that role (e.g. GCP, NIH, STU training etc.)

QI/PLD approval date = Date the QI/PLD approved the addition to the PL

Effective start date = Date that the participant's status is "active" and they can participate on the trial – it is the date that all 3 criteria were met.

- In other words, the latest date of the requested start date, date requirements met and QI/PLD approval date.

Stop dates

Requested stop date = Date the centre enters as a stop date for that participant performing that role and those duties; this will be interpreted as 11:59PM (Eastern Time) for the removal.

QI/PLD approval date = Date that the QI/PLD approve the removal from the PL

Effective stop date = Date that the participant's status is "removed" – it is the date that both criteria were met

- In other words, the latest date of the requested stop date and the date of QI/PLD approval

7.4 Minimum/Required Roles

There are **4 minimum roles that are required** for a Participants List:

- Qualified investigator (QI)
- Principal CRA (PCRA)
- Ethics CRA (ECRA)
- Principal Pharmacist (PPHARM), required if the trial involves drug

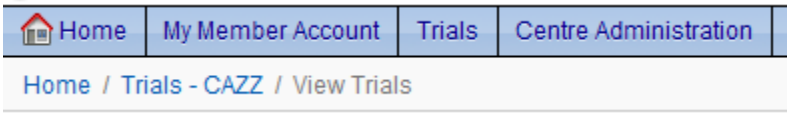
There can only be one QI, PCRA and PPHARM for a trial at each centre. There may be additional requirements on a trial by trial basis.

When creating an initial Participants List, the list will not be saved until ALL required roles have been added. If all roles are added but do not meet criteria, or are not active, then the RIPPLE side bar (located on the right hand side of the Trial PL page) will flag in red that all mandatory/required role requirements have not been met.

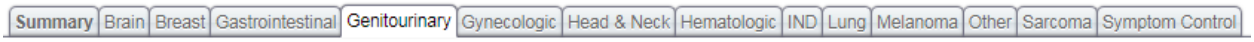
7.5 Creating a new Participants List

Reminder: *Only an RRA or a PLA assigned to that trial can create an initial PL for a trial*

- Select ***Home*** to go to the RIPPLE home page.

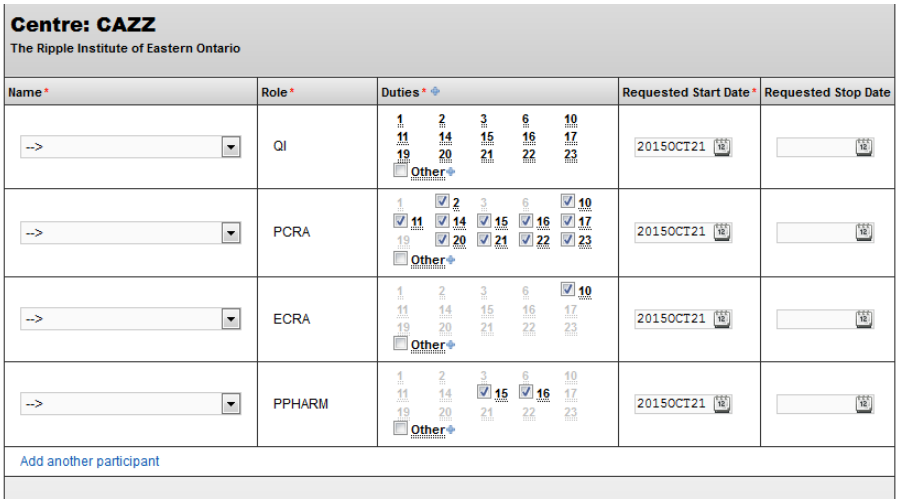


- Locate the applicable trial by selecting the ***disease site*** from the tabs and choosing the appropriate trial



- Select the ***trial code*** for the appropriate trial in the ***Trial*** column

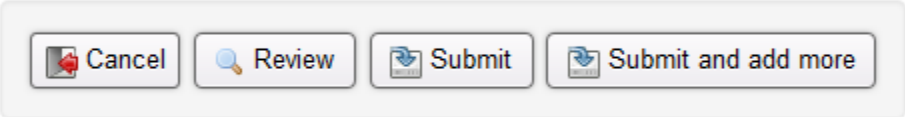
- The trial PL page will appear and the roles that are mandatory for that trial will already be populated. The duties that are permissible for these roles will also be populated. Delegated duties are restricted by role. Please refer to Participants List & Qualified Investigator Delegation of Duties available at: https://www.ctg.queensu.ca/trials/generic_forms/PL_PLCF/pl_plcf_requirements.html



- Select the names of the participants that will be assigned to each of the mandatory/required roles from the drop down menu. All active members at a centre will appear in the drop down menu
- If applicable deselect any duties. Only individuals who perform a specific duty and are appropriately qualified through training and credentialing to do so should be assigned that duty on the participants list.
- If a delegated duty is not represented by the standard dictionary of duties, please indicate it by selecting ***Other*** and providing the delegated duty under ***Specify***.
- Select the ***Requested Start Date*** (you can also enter the stop date if known) for each role

- If there are additional participants to be added click on ***Add another participant*** at the bottom of the PL and a new row will appear on the table

Once all participants have been added select one of the following options at the bottom of the page:



- **CANCEL:** Cancels and exits the Trial PL page
- **REVIEW:** Reviews the credentialing and training requirements for each of the participants being added to the Trial PL and reports a pass or fail. Once viewed you can ***Continue and Submit*** or ***Cancel***
- **SUBMIT:** Saves and Submits the PL
  - If submitting the form you will be asked to confirm you would like to submit these changes
    - Select ***Confirm*** to submit
    - Select ***Cancel*** to return to the trial PL to make changes
- **SUBMIT AND ADD MORE:** Saves and submits the PL, and then lets you continue to add more participants to the PL

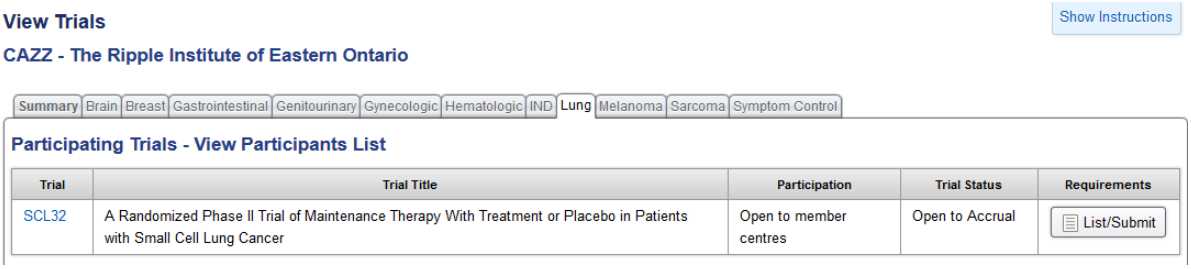
An initial PL (or subsequent changes to the PL) must be submitted or it will be removed from the system. The initial PL cannot be saved or submitted until all mandatory roles have been delegated. After the initial submission additional participants can be added and submitted at any time.

Note: A single participant can be assigned multiple roles for the same trial, but there must be a separate entry on the PL for each role (e.g. ECRA and ACRA).

7.6 Adding a Member to an Existing Participants List

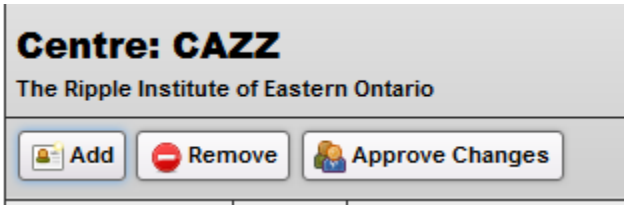
Reminder: *Only a QI, PLD, PLA or RRA can make changes to an existing PL for a trial!*

- Select ***Home*** from the RIPPLE toolbar to get to the home page
- From there select the correct disease site tab. Trials that already have a PL created at a centre will appear under ***Participating Trials – View PL*** when the disease site tab is selected.

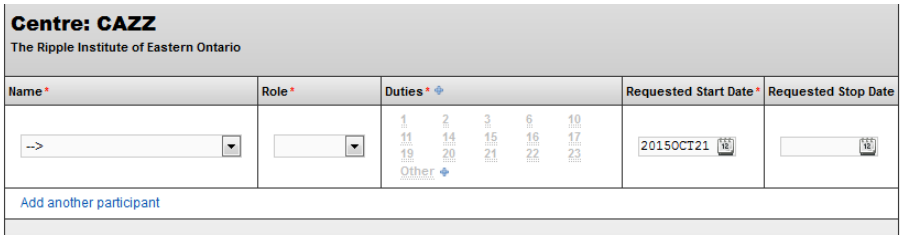


- Locate the applicable trial on the ***Participating Trials – View PL*** table and select the trial code

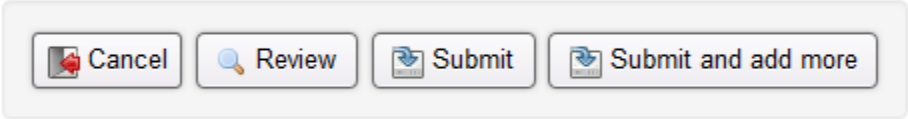
- Select ***Add*** at the top of the PL just below the centre name



- From the drop down list select the ***Member***, the ***Role*** they are performing on the trial (all duties permissible for that role will then be auto-populated), and enter the ***Requested Start Date*** (Note: Requested stop date is optional and duties should be unselected if they are not applicable for that individual).



- If there are more participants to be added select ***Add another participant*** at the bottom of the PL and a new row will appear
- Once all participants have been added select ***Review***, ***Submit***, ***Submit and add more*** or ***Cancel*** (as described in section 7.5)



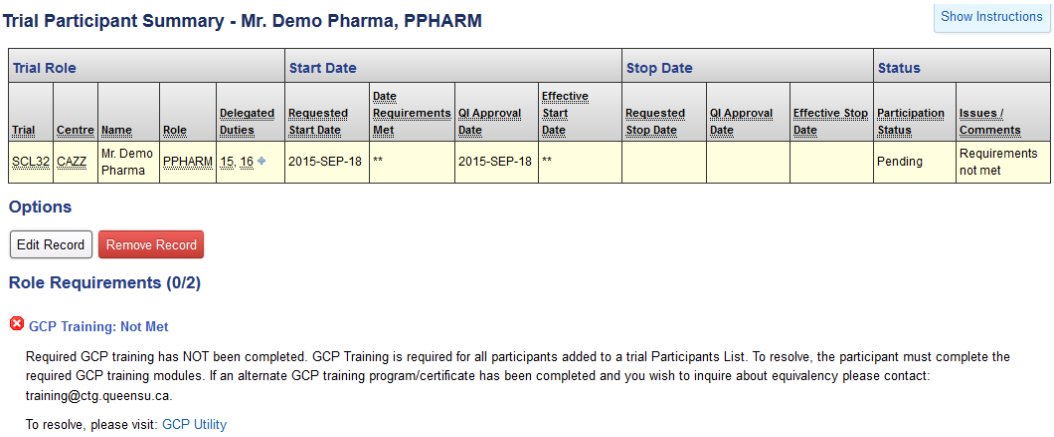
A single participant can be assigned multiple roles for the same trial, but there must be a separate entry on the PL for each role.

7.7 Performing Trial Related Duties

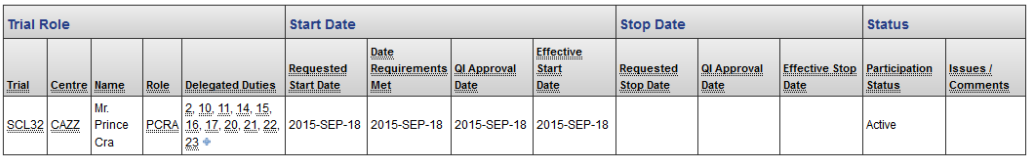
Once the PL additions have been submitted the ***Participation Status*** will be ***Pending*** until the following actions occur:

Name	Role	Delegated Duties	Requested Start Date	Effective Start Date	Requested Stop Date	Effective Stop Date	Approval	Participation Status	Issues/Comments	Action
Mr. Demo Pharma	PPHARM	15, 16	2015-SEP-18				Initial	Pending	Requirements not met	Details/Edit

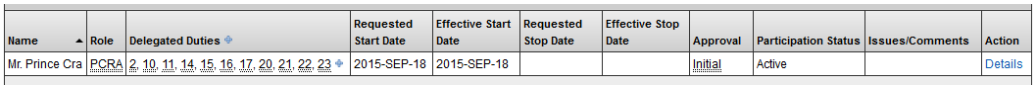
1. **Confirmation that all credentialing and training requirements have been met**
   - Selecting ***Details/Edit*** under the ***Action*** column for the individual will show the date that the requirements were met, or the details of any credentialing/training requirements that are not met and how to resolve them. (Please see section 7.9 for details on resolving missing credentialing or training requirements)



2. **Participant's role assignment for the trial is approved by the QI/PLD**
   - The QI/PLD will receive an email that an addition must be approved and they must complete this process
   - Selecting ***Details/Edit*** under the ***Action*** column will show the date the QI/PLD approved the addition



   - On the Trial PL page the ***Approval*** column will change to ***Initial***

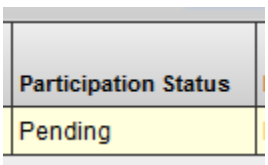


3. **The requested start date has been met**

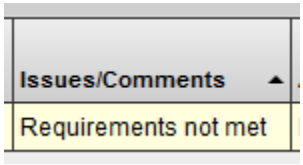
Once all 3 criteria have been met the ***Effective Start Date*** will be populated and the participant's status will change to ***Active***. The participant can now perform significant trial related duties for the trial. Once the criteria have been met, the participant will receive an email notification that they are now active on the trial.

Criteria Not Met?

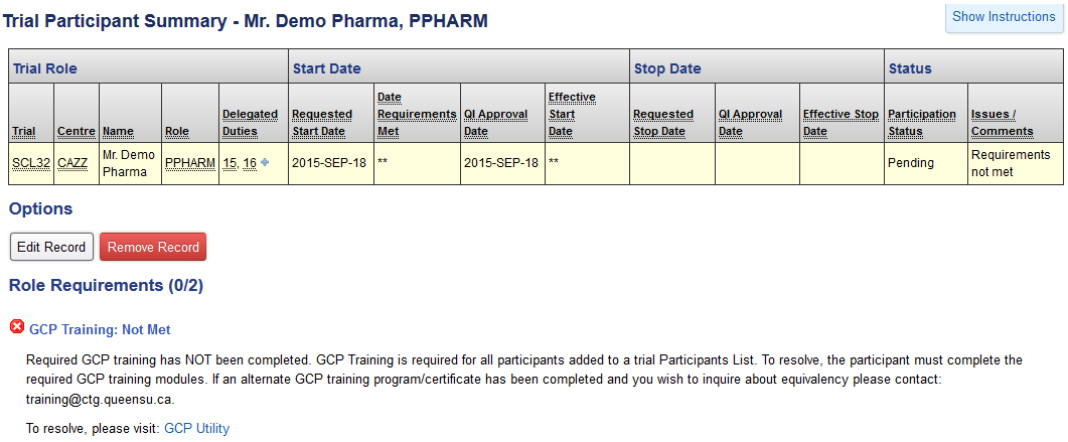
- If the 3 criteria are NOT met then the ***Participation Status*** on the Trial PL will remain as ***Pending***



- If The QI/PLD approval has not been obtained then the approval column on the Trial PL page will show ***None*** and the ***Issues/Comments*** column will document ***Initial approval required***.
    - Selecting the ***Details*** link in the ***Action*** column will show that the ***QI/PLD Approval Date*** column is empty
- If the required credentialing criteria have not been met, on the Trial PL page the ***Issues/Comments*** column will document ***Requirements not met***.



    - Selecting ***details*** in the ***Action*** column will show that the ***Date Requirements Met*** column is empty and below the table it will specify which of the requirements have not been met.

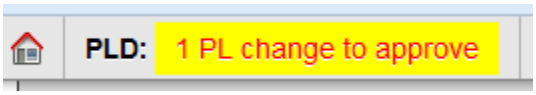


    - The Participant will also automatically receive an email notifying them that they have been added to a trial PL but do not meet the training/credentialing requirements. There will be a link to the applicable PL in the email
    - This email is sent as soon as the Participant is added to the PL and the PL is submitted
    - **Note that the participant is non-compliant if they start performing their delegated duties prior to QI/PLD approval**

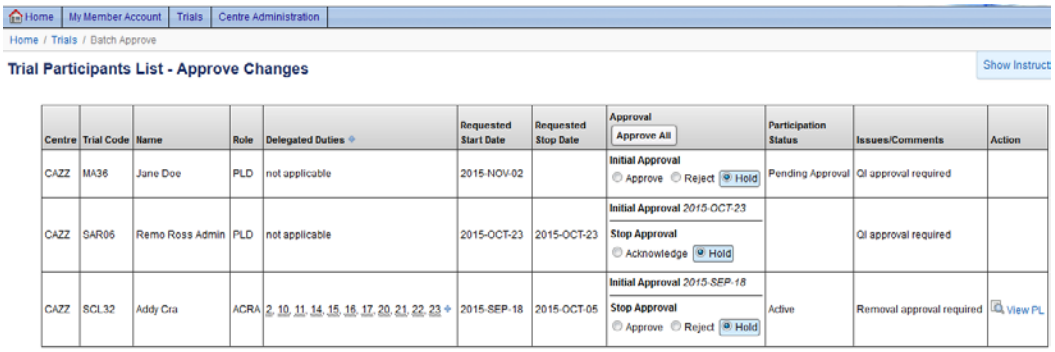
7.8 QI/PLD Approvals

When a PL is created (or subsequent changes to an initial PL are made) an email notification will be sent to QI/PLD indicating that there are PL additions/removals requiring approval. An email will also be sent to the QI/PLD each Monday morning if there are any PL changes pending approval for their trials. The QI/PLD will then:

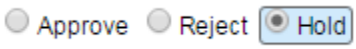
- Either sign in to RIPPLE directly or click on the RIPPLE link in the email notification they receive. They can then sign in to RIPPLE using their CCTG user ID and password
- At the top left of the QIs/PLDs main page the tool bar will indicate if there are any changes to approve and how many there are (this includes any approvals for any of the trials for which they are assigned as the QI/PLD)



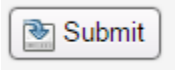
- The QI can click on the link in the tool bar to access the QI/PLD approval page
- All PL changes (additions and removals) for all trials the QI/PLD is assigned to will appear on a single page



- The QI/PLD can change the role, duties or requested start and stop dates prior to approving
- If satisfied with the PL changes the PI/QLD can either click ***Approve***, ***Reject*** or ***Hold*** for each individual PL change



- If there are multiple changes to approve the QI/PLD can also select ***Approve All*** at the top of the ***Approval*** column. This allows them to approve all changes at one time rather than approving each one individually.
- Click the ***Submit*** button (Note that ***Submit*** MUST be selected to submit all approvals)



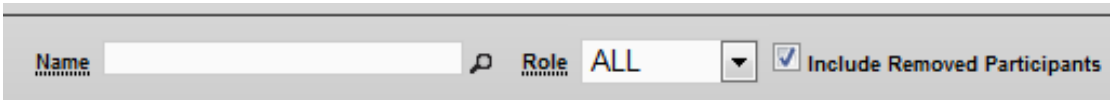
- If neither ***Approve*** or ***Reject*** are selected (i.e. ***Hold*** is chosen) the records will remain unapproved (pending) and will remain on the QI/PLD approval page for future approval
- If all pending changes were either approved or rejected a notice will appear on the same page that there are no longer any outstanding PL changes to approve
- Once approved, the QI/PLD approval date will automatically be populated on the trial PL and if the other criteria have been met the effective start or stop date will be populated
- The participant status will also change to ***Active*** if it is an addition and ***Removed*** if it is a removal.

Trial Role					Start Date				Stop Date			Status	
Trial	Centre	Name	Role	Delegated Duties	Requested Start Date	Date Requirements Met	QI Approval Date	Effective Start Date	Requested Stop Date	QI Approval Date	Effective Stop Date	Participation Status	Issues / Comments
SAR06	CAZZ	Mr. Prince Cra	PCRA	2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23	2015-AUG-19	2015-AUG-19	2015-AUG-19	2015-AUG-19				Active	

If a QI/PLD rejects the PL delegations then the participant's record will change from ***Pending*** to ***Removed*** and the participant will receive an email notification indicating that their participation on the trial was not approved.

If the QI is unavailable (i.e. on vacation, etc.) and there is no PLD assigned for the trial the changes will remain pending until the acting QI returns and approves them as it cannot be done by anyone in their absence.

Once a participant has been removed from a trial the status of their record becomes ***Removed***. These participants can be included on the Trial PL by selecting the ***Include Removed Participants*** checkbox located near to top right of the Trial PL table.



7.9 Credentialing and Training Requirements

When a participant is added to a Participants List for a trial RIPPLE performs a series of ***Requirements Met*** checks. There are 2 types of requirements:

- **Standard:** This credentialing/training is linked to the participant's membership record (instead of trial specific training which is linked to a specific trial and the PL for that trial). Some examples include:
  - Investigator CVs
  - GCP/Division 5 Training
  - Ethics Training (NIH Protection of Human Research Participants)

- **Trial Specific:** Many trials in RIPPLE have trial specific training or credentialing that must be completed in addition to the generic credentialing. This training is linked to the Participants List for a specific trial rather than the to the membership record. It includes uploaded documents and/or links to completed training in other systems. Some examples of this include
  - Study Acknowledgement/Disclosure Form
  - Financial Disclosure Form
  - Site Training Utility (STU)

A participant can view their own credentialing and training record in 2 ways:

- Selecting the ***Participation Requirements*** tab in the membership account section of RIPPLE will show Standard training
  - This can be found under ***My Member Account→ Account Information→ Participation Requirements***
- By viewing the Participants List for a specific trial
  - Selecting ***Details/Edit*** under the ***Action*** column for an individual will show what training has been completed or is outstanding

The RRA at the site can also view the generic credentialing and training record for any member at their centre following the same steps.

To determine which credentials and/or training are required for participants refer to the credentialing requirements table for the trial.

- This can be found by selecting the ***List/Submit*** button under ***Requirements*** on the ***View Trials*** page for the particular disease site (see section 7.2)

Trial Participation Requirements - SCL32

Trial Complexity Level: 1

CAZZ - The Ripple Institute of Eastern Ontario

Standard Training & Credentialing Requirements

Refer to https://www.ctg.queensu.ca/trials/generic_forms/PL_PLCF/pl_plcf_requirements.html.

Trial Requirements

Requirements / Roles	QI	PCRA	ECRA	PPHARM	SI	ACRA	PHARM	PTECH	Duty 1	Duty 3
GCP Training	!	!	!	!	!	!	!	!		
Health Canada Division 5 Training	!	!	!	!	!	!	!	!		
NIH Training	!				!					
Site Training Utility	!									
Curriculum Vitae	!				!					
Investigator Type Requirement	Type 1 Investigator								Type 1 Investigator	Type 1 Investigator
QIU Form	!									
Study Acknowledgement/Disclosure	!									

! = Required, click to submit/upload

Complexity Description

Level 1: High Risk and Complexity; Trials that require sub-specialization within the field of oncology, including experience in the conduct of clinical research evaluating highly complex interventions.

7.9.1 Completing Credentialing/Training Requirements

RRAs can upload documents for any member/participant at their centre for any trial. The member themselves can also upload documents for their own account/record. Please note that PLAs and PLDs can only upload documents for trials that they have been assigned to.

Once the required credentialing/training requirements have been identified there are several ways to confirm if the participant has met the requirements and to complete the requirements.

7.9.1.1 Standard Training & Credentialing Requirements Table

Training completed via CCTG systems

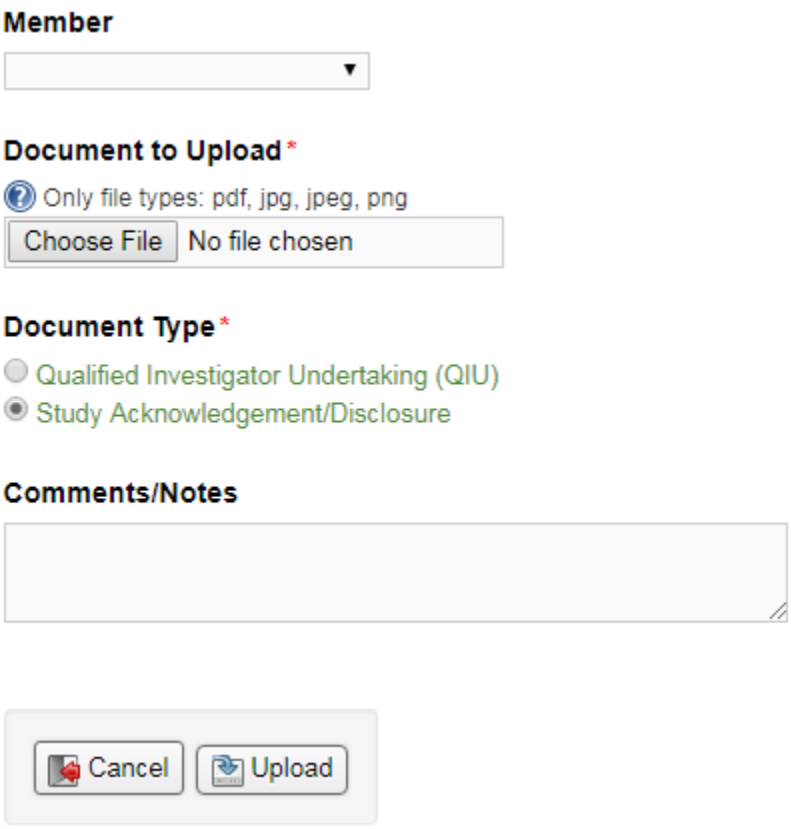
- Select the required icon for the training to be completed (for example Site Training Utility) or the document to be uploaded (for example, Financial Disclosure)

- Enter the User ID and password and follow the link(s) to complete the training if it is a training module – completion of the training module/system will be checked in the RIPPLE system

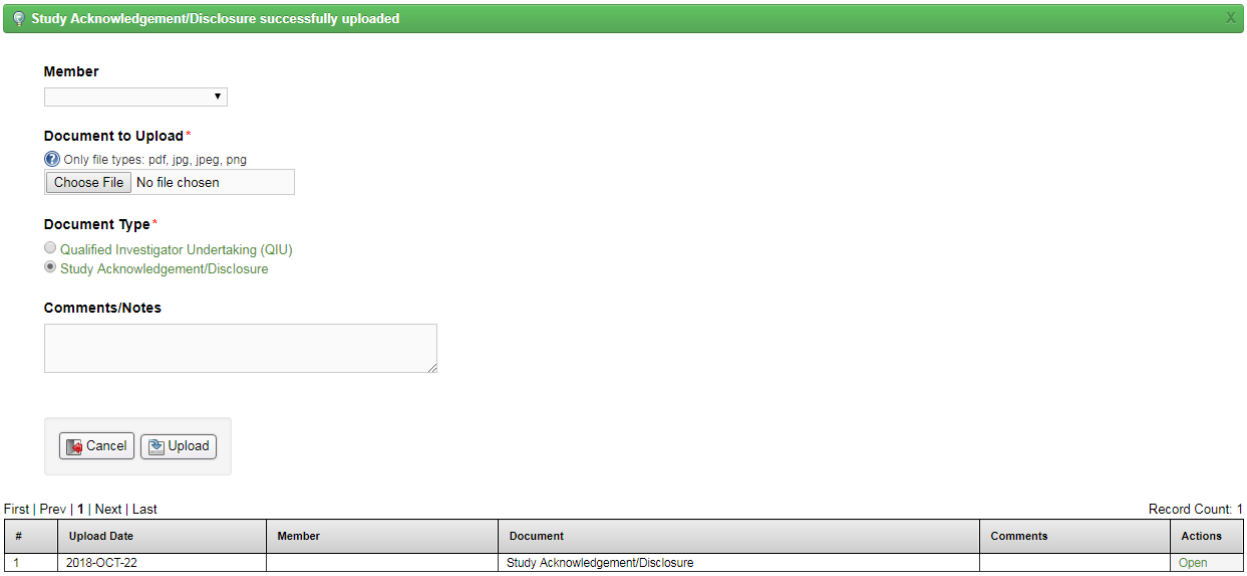
Uploading documents

- To upload the document select the required icon that corresponds to the requirement (QIU form, FD form etc.) and to the member (QI, SI, etc.)

- The upload page for the chosen document will load (For example the Study Acknowledgement Disclosure Form)



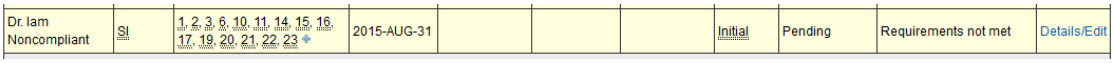
- Ensure the correct member is chosen and click ***Choose File*** to locate and attach the file
- Select the correct document under ***Document Type***
    - Only pdf, jpg, jpeg and png files are accepted
- Enter any comments/notes as needed
- Select ***Upload***
- If the document was successfully uploaded a green box will appear indicating this. The document will also appear on the bottom of the page where it is available for viewing



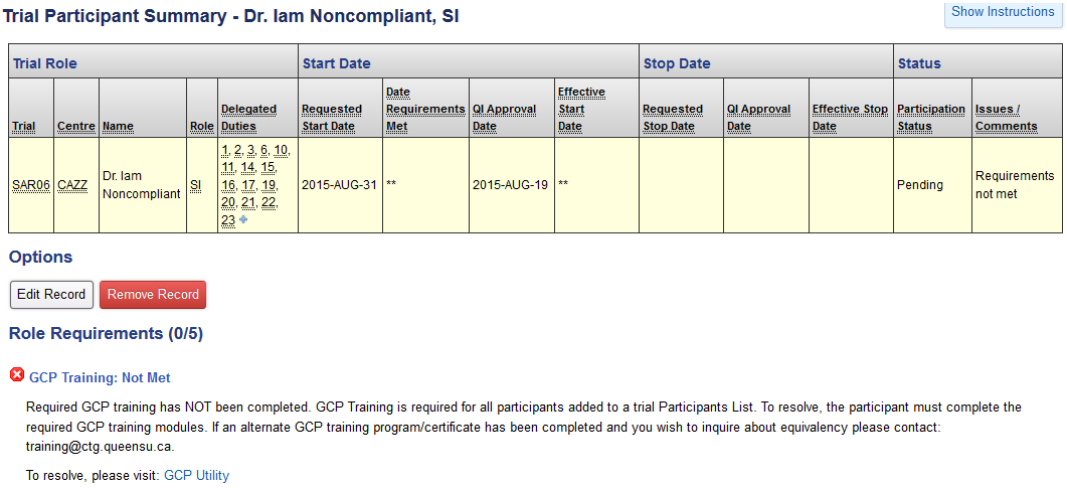
- **Note:** Please ensure that documents are uploaded to the participant's/member's account and NOT to the RRAs/PLAs/PLDs account if they are the one uploading the document.

7.9.2 Trial Participants List

- If the participant has been added to the trial PL and they do not have all credentialing/training required for that role on that trial it will indicate ***requirements not met***
- Click on ***Details/Edit*** in the right hand column of the participant entry.



- Under ***Role Requirements*** the credentialing/training item that has not been uploaded/met will have a red "X" beside it



- Under the name and description of that requirement (for example GCP Training), there will be a link to complete the training or to upload the missing document
- Select this link

- Enter the User ID and password and follow the link(s) to complete the training

- If a document needs to be uploaded follow the process outlined in section 7.9.2.1
- If all documents and training have been successfully completed all of the ***Role Requirements*** will indicate ***Passed*** and the participant's status will change to ***Active*** (assuming that all criteria have been met)

Role Requirements (9/9)

GCP Training: Passed

All required GCP training has been completed.

NIH Training: Passed

NIH Protection of Human Research Participants Training has been completed as required

CTEP Investigator Number: Passed

This investigator has a CTEP investigator number

Curriculum Vitae: Passed

A current CV has been received and approved for this investigator.

Investigator Type Requirement: Passed

This investigator is credentialed as a Type 1 or Type 2 Investigator and therefore meets the requirements to be active on this trial (Trial Complexity Level 2).

Study Acknowledgement/Disclosure: Passed

The Study Acknowledgement/Disclosure Form has been received for this Qualified Investigator.

Site Training Utility: Passed

The training required for this trial in the Site Training Utility has been completed.

Health Canada Division 5 Training: Passed

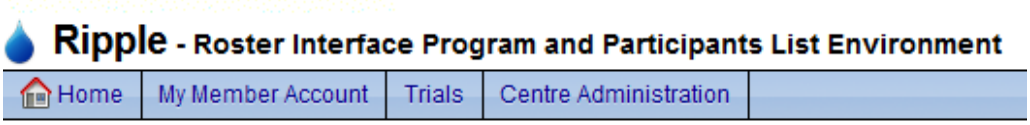
All required Division 5 training has been completed.

QIU Form: Passed

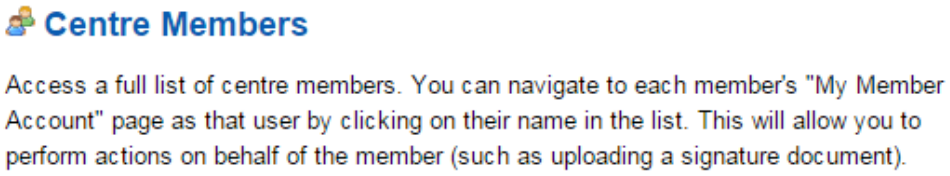
The QIU Form has been received for this QI

7.9.2.1 Member Account

- Members themselves can complete training and upload documents through their membership record (please refer to section 3.3.2 for instructions)
- Standard (i.e. not trial specific) credentialing/training documents may also be uploaded through the member's account by the Remote Roster Administrator.
    - Select ***Centre Administration*** from the top tool bar



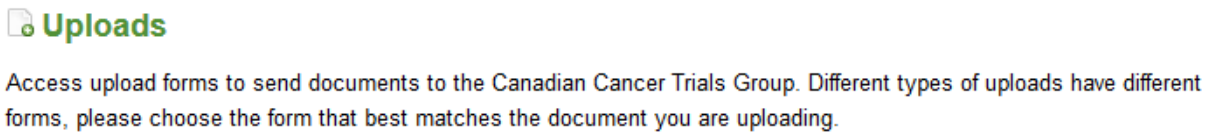
- Select Centre Members



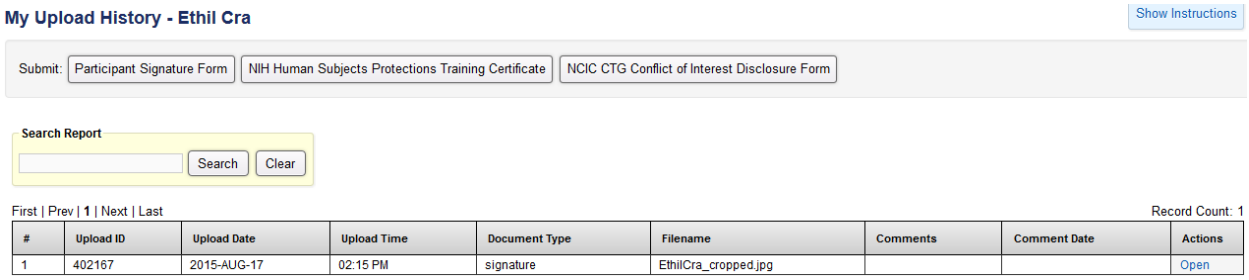
- Select the participant that has documents to be uploaded

- A pop up will appear, select ***View Account***

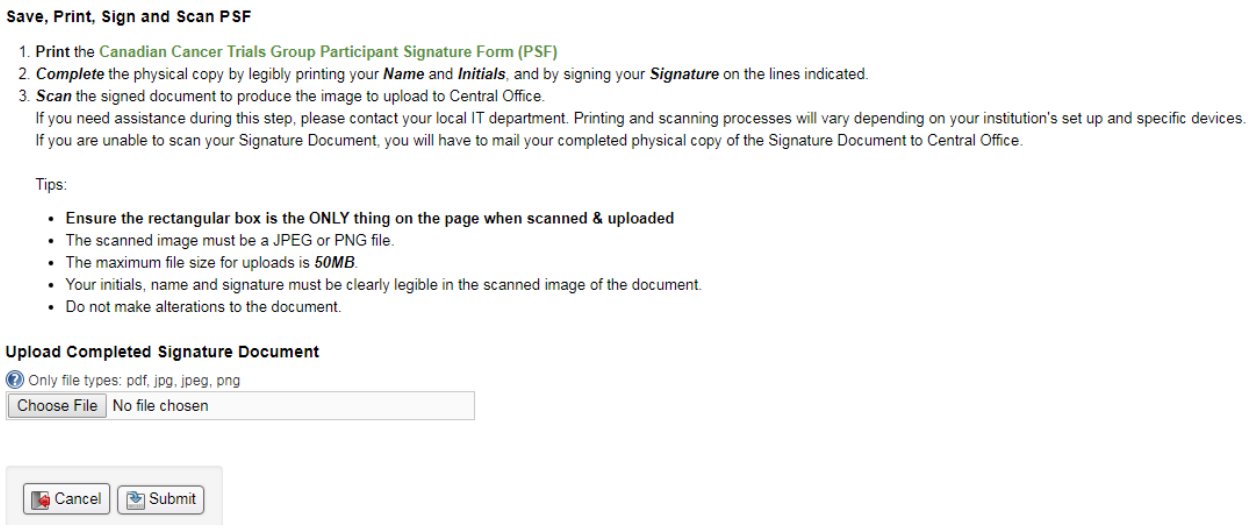
- Select ***Uploads***



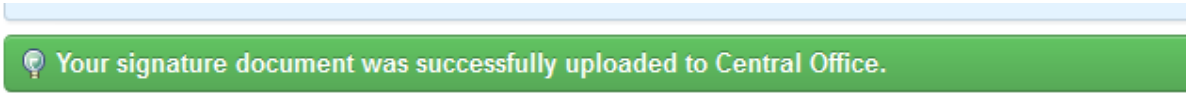
- The ***My Upload History*** page will appear



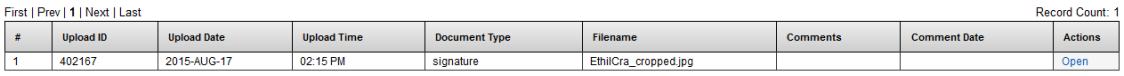
- Select the form to upload
- The upload page for the chosen document will appear (For example the Participant Signature Form)



- Select ***Choose File*** to locate and attach the file
  - Remember that it must be a JPEG or PNG file
- When the correct file is chosen select ***Submit***
- If the document was successfully uploaded a message will appear at the top of the page indicating this



- When the upload has finished the uploaded document will appear at the bottom of the page



7.9.3 STU training

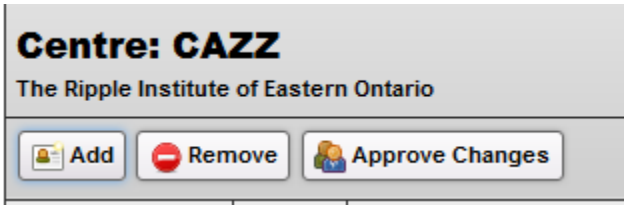
For the majority of trials, trial specific training in STU by the trial QI is mandatory. Any STU related requirements will be outlined for each trial in the credentialing requirements table for that trial. RIPPLE will check the STU system as a component of the ***Requirements met*** checks to ensure that STU training has been completed for each individual for which it is required.

In order to access STU for your trial you must already have been added to that Trial PL (you will be ***Pending***). If a Trial PL has not yet been created at your centre and you need to access STU training for that trial immediately please contact the applicable trial team.

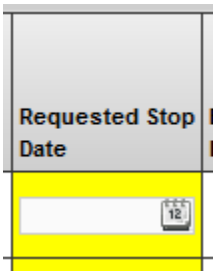
7.10 Removing a Participant from a Participants List

7.10.1 Removal from a Specific Trial

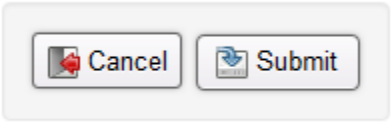
- Trials in RIPPLE
  - Go to the ***Trial PL*** page in RIPPLE
  - Select ***Remove*** at the top of the PL just below the centre name



- Enter the appropriate ***date*** in the ***Requested Stop Date*** column for the applicable participant/role



- Select ***Submit*** at the bottom of the page



- A notification will go to the QI/PLD to approve this removal
  - Once they have approved the removal and the requested stop date has been achieved the participant's status will change to ***Removed*** and an ***Effective Stop Date*** will be populated.
  - Until the QI/PLD has approved the removal, the ***Issues/Comments*** column will indicate ***Removal Approval Required***

- **Non-RIPPLE trials**
  - Submit a paper Participants List Change Form (PLCF) with requested stop date

7.10.2 Removal from all trials

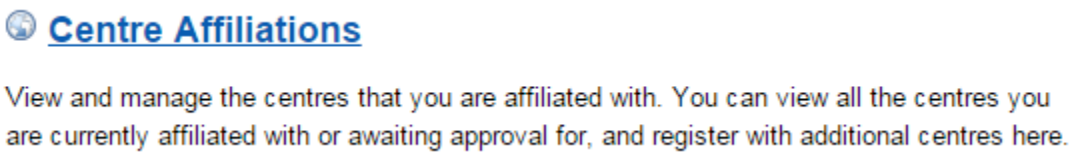
When a participant leaves a centre there are two options for removing them from the Participants List.

Removal of a participant from a centre and each Trial PL

- Select ***Centre Administration*** from the top toolbar and then ***Centre Members***
- Select the ***Member*** from the list

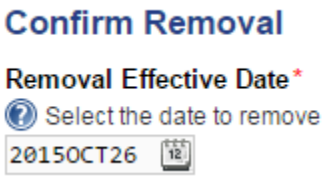
o A pop up box will appear, select ***View Account***

- Select Centre Affiliations

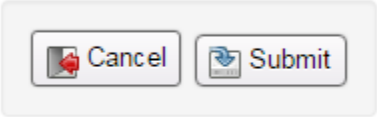


- Select Remove Affiliation

- Enter Removal Effective Date



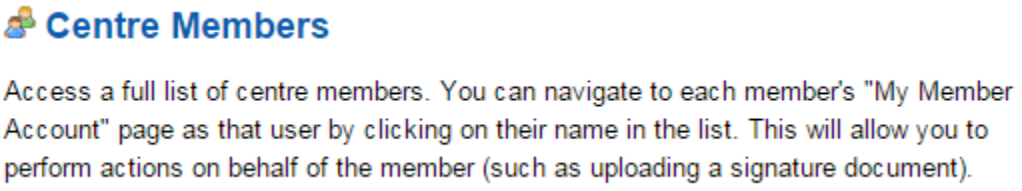
- Select ***Submit***



- A notice that this will be processed by CCTG will appear
- For non-RIPPLE trials please submit paper PLCFs

Removal of a participant from the centre and removal from all RIPPLE PLs

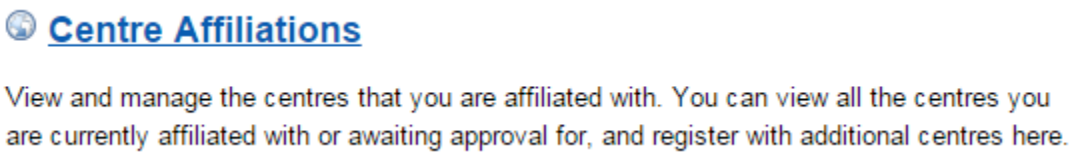
- Select ***Centre Administration*** and then ***Centre Members***



- Select the ***Member*** from the list

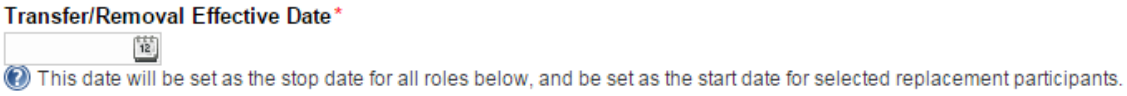
- A pop up box will appear, select ***View Account***

- Select ***Centre Affiliations***

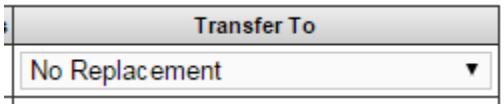


- Select ***Transfer/Remove Roles***

- Enter the Transfer/Removal Effective Date



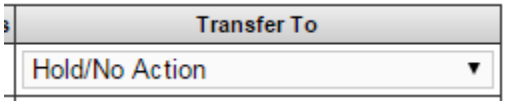
- From the drop down menu select either ***No Replacement*** or the ***name of another person*** who will be taking over this role for the correct trial



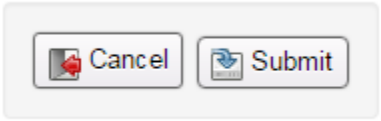
- The ***Removal Effective Date*** will be automatically added as the ***Requested Stop Date*** for the person that is leaving on each applicable trial PL. It will also be added as the ***Requested***

Start Date on each trial PL for the person that is replacing them (However this date may be overwritten)

- If ***Hold/No Action*** is selected instead of an alternate participant a Requested Stop Date will not be added for that trial



- Select ***Submit***



- A notice that this will be processed by CCTG will appear
- Notifications will be sent to the applicable QIs/PLDs to approve the removals and additions for each applicable trial
- All regular criteria must be met for the replacement participant being added prior to their addition being effective (i.e. Requested Start Date met, credentialing requirements met and QI/PLD approved).
  - Please note that if the role being transferred is a mandatory role, the replacement cannot become ***Active*** in that role unless the QI/PLD has approved the removal of the current active participant in that role.

Reminder: Changes made to the PLs by the RRAs, PLAs or PLDs are **NOT** effective right away! All credentialing requirements for the designated role must be met (for a PL addition), the requested start or stop date must be reached and the QI (or PLD if applicable) must approve the additions/removals prior to their being effective.

For any trial not in RIPPLE a paper PLCF needs to be submitted for removal.

If the PLD has made the change to the trial PL then the change will not require QI/PLD approval. However all training/credentialing requirements must be met for a PL addition, and the requested start or stop date must be achieved prior to a change in the participant's status.

Notes:

If the RRA has entered the removal effective date then no further action is required to remove the Participant from the centre.

If a Participant has left a centre and a period of time has passed without removal from the PL then the PL should be updated as soon as possible. Additional actions may be required per local policy depending on the situation. If possible use the date that the Participant left the centre or discontinued on a trial as the effective stop date. If this is unknown then use the date that the PL was changed.

7.10.3 Removal of a Participant with a Required Role

When a required Participant role is removed a flag will appear on the Trial PL page on the right hand side. This flag will indicate that there is a missing mandatory role for the trial. When this happens a notification will be sent to the trial PCRA. If the missing role is a QI then CCTG will also be informed for further action.

There can only ever be one of each of the mandatory roles (QI, PCRA, PPHARM) active at one time. If a new mandatory role needs to be added then the changes should be made in advance whenever possible.

This will ensure that there is time for a QI/PLD to approve the changes and sufficient time to resolve any potential credentialing/training requirements.

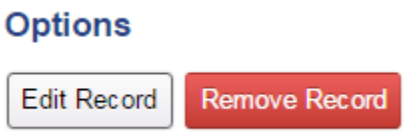
To add a new mandatory Participant, the current Participant in that role must be removed.

- Please note that the removal of the current PCRA/PPHARM/QI must be approved by the QI/PLD before the new one can become active

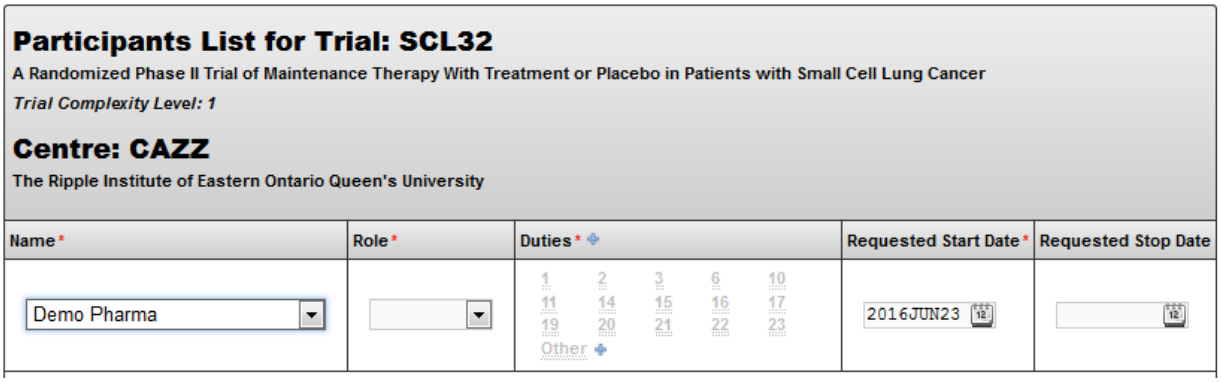
7.11 Amending the Participants List

7.11.1 Amending a Participants List that has not yet been approved by a QI/PLD:

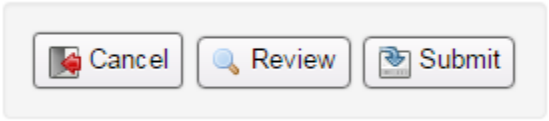
- A new record does not need to be created
- Select ***Details/Edit*** in the far right hand ***Action*** column for that Participant on the PL
- Once in the Participant's record select ***Edit Record***



- The Participant's information can now be edited. For example, changing the requested role, changing the start date or deselecting delegated duties can all be done from here



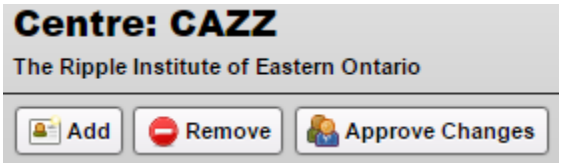
- Select ***Submit*** once the required changes have been made



- The edited record will then be submitted to the QI/PLD for approval.
    - Remember that a participant is not eligible to perform trial related duties if the Requested Start Date has passed and the QI/PLD has not yet approved it

7.11.2 Amending a Participants List that has already been approved by a QI/PLD

- The original record will need to be removed and a new record added
- Select ***Remove*** at the top or bottom of the PL



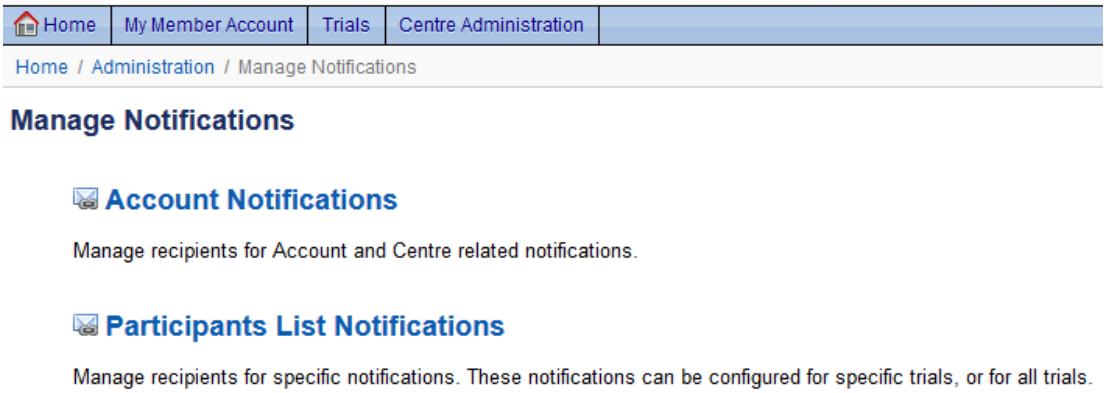
- The ***Requested Stop Date*** column will change to yellow and the date can now be entered

- To enter the updated record follow the same process as adding a new Participant and enter the updated information
- Both the removal and addition will require QI/PLD approval
    - Note that the participant is non-compliant if they start performing their delegated duties prior to QI/PLD approval
- If the change in role/duty is being completed retrospectively, the Requested Stop Date of the current record and the Requested Start Date of the new record should reflect the Participant's actual role and duties on the trial over time.

From a compliance perspective we recommend creating a note to file to explain how issues with delegation were noticed, how the PL was corrected in RIPPLE, and outlining a process for ensuring duties are appropriately delegated in the future.

7.12 Notifications

A Member may receive notifications throughout the course of a trial. To view notifications ***select Centre Administration*** and then ***Manage Notifications***. There are 2 types of notifications: ***Account Notifications*** and ***Participants List Notifications***.



7.12.1 Account Notifications

These notifications relate to specific member accounts and centre related communications.

The following notifications are available:

1. **Centre Registration Approved-** Sent to a participant when their registration with a centre has been approved
2. **Centre Registration Received-** Sent to a participant when their request to register with a center has been received
3. **Centre Registration Rejected-** Sent to a participant when their request to register with a centre has been rejected
4. **Registration Approved-** Sent to an applicant when their request for an account has been approved
5. **Registration Received-** Sent to an applicant when their request for registering a new account has been received
6. **Registration Rejected-** Sent to an applicant when their request for an account has been rejected
7. **Registration Reminder-** Sent to an RRA when there are new registrations awaiting their approval
8. **Account Change Request-** Sent to the RRA and the participant when there has been a request to change their account information
9. **Account Change Request Result-** Sent to the RRA and the participant when the requested changes have been approved
10. **Investigator Registration Result-** Sent to the RRA and the participant when an investigator registration request has been reviewed by central office and the results are available
11. **Investigator Registration Submitted-** Sent to the RRA and the participant when an investigator registration has been submitted for central office review
12. **Document upload-** Sent to the Roster team at CCTG. When a document is uploaded for a participant. There is an option to have this notification sent to the participant and the RRA at a centre as well.
13. **Participant Signature Required Reminder-** Sent to the participant when they are required to submit a signed signature document

7.12.2 Participants List Notifications

These notifications relate to the participants list and managing aspects of it.

There are 7 different notifications:

1. **Participants Added But Requirements Not Met –** Sent to the participant when the participant has been added to a trial PL but does not meet one or more of the credentialing/training requirements to be Active on that trial
2. **Participant Now Active on Trial –** Sent to the participant when the participant becomes Active on a trial PL
3. **Participant No Longer Active on Trial –** Sent to the participant when the participant is no longer active a trial PL
4. **Participant Addition on Trial Not Approved –** Sent to the participant when the addition of a participant to a PL was declined by the QI/PLD.
5. **PLD Agree/Reject Attestation Recorded -** Sent to the QI when the participant has accepted or rejected the PLD assignment
6. **PLD Agree/Reject Attestation Reminder -** Sent to the participant when the participant has not yet accepted or rejected the PLD assignment
7. **PLD Agree/Reject Attestation Required -** Sent to the participant when they are initially assigned the PLD role
8. **Participants List Batch Approval Reminder –** Sent to the QI/PLD to remind them of all outstanding approvals for PLs for trials for which they are responsible.

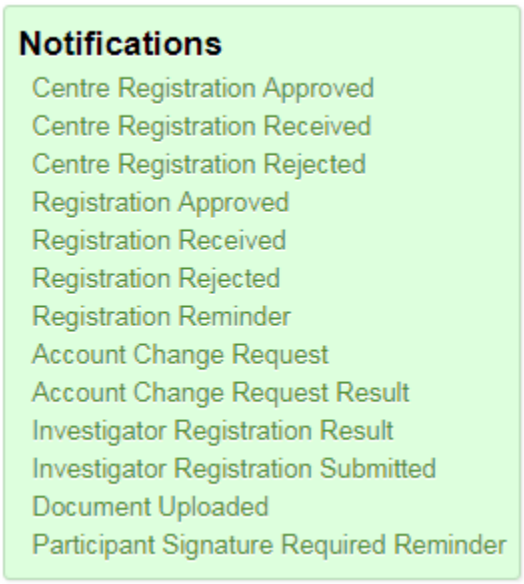
9. **Participants List Required Roles Met -** Sent to the PCRA when the initial Participants List for a trial is completed (i.e. all required roles are active)
10. **Participants List Required Roles Missing –** Sent to the PCRA when the Participants List does not have active participants in all mandatory roles

7.12.3 Viewing Notifications

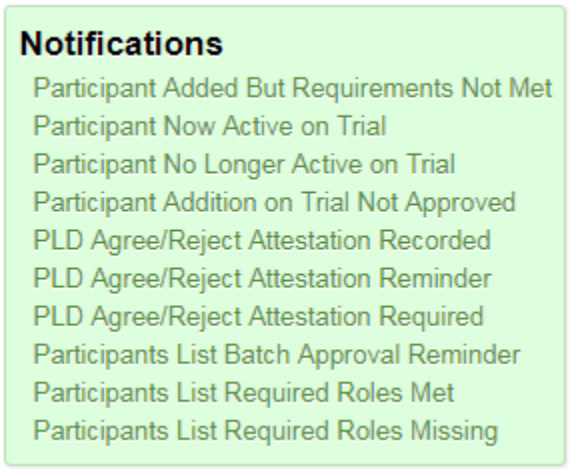
To see who the PL notifications go to and what the message says please do the following:

- Select ***Manage Notifications*** under ***Centre Administration*** in the top toolbar
- Go to the Participants List Notifications page or the Account Notifications page and select the notification of interest

Account Notifications



Participants List Notifications



- For each selected notification you will see:
  - A description of the notification/reminder
  - The message included in the email notification
  - The recipients (Left hand column indicates who the message is sent to automatically, the right hand column lists other roles to whom the message can be sent for that trial or for all trials at your centre)

7.12.4 Changing Notifications

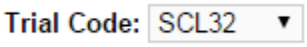
The RRA can make changes to ALL notifications at their centre. The PLD and PLA can only make changes to notifications for their assigned trials.

For each notification the default recipient is listed in the left hand column and these cannot be changed locally. However, in the right hand column you may select the additional roles you would like this notification/reminder to be sent to.

The Participants list notifications also have the option of selecting which trial the notifications can be sent for.

- If you select ***All Trials*** these additional recipients will receive notifications for all trials at your centre.

- Alternatively you may select a ***specific*** trial at the top of the page (to the right of the centre) and these additional email recipients will be for that trial only

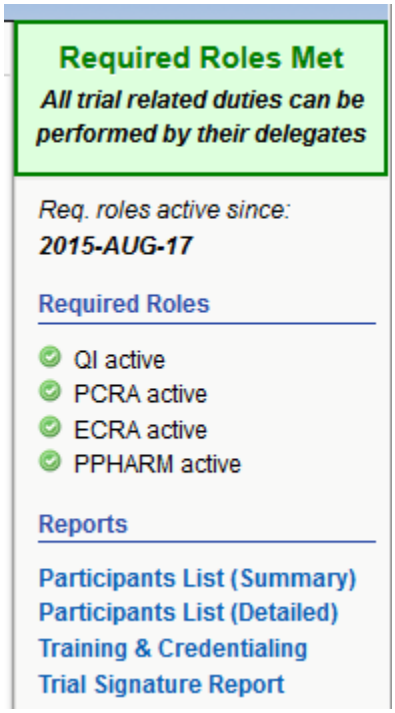


7.13 Local Filing of RIPPLE Essential Documents

Centres are not required by CCTG to keep printouts of the PL reports or trial signature reports from RIPPLE. However hard copies of these reports (including full PL history) may be required for monitoring, audit or inspection. Centres should ensure they continue to maintain and file credentialing documents uploaded into RIPPLE (e.g. CVs, Participant Signature Forms, Financial Disclosure forms) per standard local policy.

7.14 Reports

On the far right side of the Trial PL page there are reports that can be run by the centre for that specific trial. They can be found under ***Reports***. Any individual at a centre can run these reports. Please refer to appendices II-IV for full versions of these reports.



- **Participants List (Summary) Report-** Including all participants for a trial, the designated roles, and delegated duties as well as effective start and stop dates; ordered by effective start date, role (required roles are first and then additional roles), and name.
- **Participants List (Detailed) Report -** Separated into active/pending/removed participants and then ordered by effective start date, role (required roles are first and then additional roles), and name
- **Training & Credentialing Report**- Lists Investigators and Clinical Trials Personnel at your centre for a particular trial. Report shows all training requirements and when they were completed as well as any training that is outstanding; ordered by effective start date, role (required then additional), and name
- **Trial Signature Report**- Includes participant signatures and initials for all participants on the trial (includes all active, pending and removed participants). Signatures and initials are obtained from the Participants Signature Form that was uploaded into each participant's membership account; separated into participant with PSF and those without and then ordered by name

8 APPENDIX I – RIPPLE Roles Summary

RIPPLE Roles Summary

The following table summarizes RIPPLE Roles in terms of their definition, requirements and permissions within RIPPLE.

RIPPLE Role	Definition	Requirements	Membership			Participants List								
			Manage Account	Upload Member Documents	Approve Centre Members	Upload Trial Credentialing Documents	View Trial PL & Reports	Create New PL	Edit PL	Approve PL	Assign Ripple Roles	Approve PL Delegate
Member	Any individual employed at a CCTG Member Centre, or at a participating or collaborating institution, group or other organization involved in the conduct of NCIC CTG clinical trials that has a registered and approved CCTG Member Account	Approved Centre Member	✓	✓			✓	✓				
Qualified Investigator (QI)	The investigator that is responsible to the sponsor for the conduct of the clinical trial at the centre or institution	Member; 1 per Trial & Centre; Credentialed as per CCTG requirements	✓	✓			✓*		✓	✓**	✓**	✓**
Remote Roster Administrator (RRA)	A Member designated by the centre and approved by CCTG to administer the centre's membership roster (including approving new Members at their centre)	Member; 2-3 per Centre; Approved by Centre Rep***	✓*	✓*	✓		✓*	✓	✓			✓
Participants List Delegate (PLD)	A Member designated by the centre and approved by the Trial QI to be responsible for the delegation and approval of trial related duties of the Trial PL in RIPPLE	Member; 1 per Trial & Centre; Approved by Trial QI	✓	✓			✓*	✓		✓**	✓**	✓**
Participants List Administrator (PLA)	A Member designated by the centre to create and administer the Trial PL in RIPPLE	Member; Assigned by Trial & Centre	✓	✓			✓*	✓	✓**	✓**		✓**

* permission applies to their own Account as well as Accounts of other Members at their Centre

** permission applies to their assigned trials

*** individual at the centre with overall responsibility for liaising with the CCTG Central Office and functions as the overall "Qualified Investigator"

Version Date: 2015JUN10

Page 1 of 1

9 APPENDIX II – Participants List (Summary) Report

Participants List for Trial [Code] (Summary)
Trial title according to the protocol.
Trial Complexity Level.
Maintained by CCTG

Centre Code: [Code]
Legal centre name according to the Centre Agreement.
Maintained by NCIC-CTG

Current Qualified Investigator	
The Current QI for the trial will be listed as Last Name, First Name. If there is no current QI then the pending QI will be listed.	Effective start and stop dates appear based on the dates entered in the trial PL.

Investigators

Name & Role	Delegated Duties	Signature On File	Effective Dates
Lists all investigators entered in the trial PL. Name displays as Last Name, First Name with Role. Ordered by Effective Start Date, Role, Name. If pending then (Pending) appears beside Role. If removed then (Removed) appears beside Role	Duties appear based on duties delegated in the trial PL. Ordered by Duty #. If there is an 'Other' Duty then Specify appears with the duty listed.	Required appears when there is no PSF on file. Complete appears when a Participant Signature Form has been submitted but not yet reviewed/approved by NCIC-CTG. Date [YYYY-MON-DD] appears when a PSF has been submitted and reviewed/approved by NCIC-CTG. The date is the PSF upload date.	Effective start and stop dates appear here based on the dates entered in the trial PL. If pending then *Effective dates not available* will appear here. If active then *[YYYY-MON-DD] to present* (or to *[YYYY-MON-DD]* if there is an Effective Stop Date) will appear. If removed (and was active at some point) then *[YYYY-MON-DD] to [YYYY-MON-DD]* will appear. If removed (and was never active) then *Never effective, removed on [YYYY-MON-DD]* will appear.

Clinical Trial Personnel

Name & Role	Delegated Duties	Signature On File	Effective Dates
Lists all CTP (CRAs, Pharms, Others) entered in the trial PL Name displays as Last Name, First Name with Role. Ordered by Effective Start Date and role (PCRA/ECRA/PPHARM then the rest). If pending then (Pending) appears beside Role. If removed then (Removed) appears beside Role.	Duties appear based on duties delegated in the trial PL. Ordered by Duty #. If there is an 'Other' Duty then Specify appears with the duty listed.	Required appears when there is no PSF on file. Complete appears when a PSF has been submitted but not yet reviewed/approved by NCIC-CTG. Date [YYYY-MON-DD] appears when a PSF has been submitted and reviewed/approved by NCIC-CTG. The date is the PSF upload date	Effective start and stop dates appear here based on the dates entered in the trial PL. If pending then *Effective dates not available* will appear here. If active then *[YYYY-MON-DD] to present* (or to *[YYYY-MON-DD]* if there is an Effective Stop Date) will appear. If removed (and was active at some point) then *[YYYY-MON-DD] to [YYYY-MON-DD]* will appear. If removed (and was never active) then *Never effective, removed on [YYYY-MON-DD]* will appear.

Role and Delegated Duty Descriptions *A description of all roles and duties will always appear at the end of the Participants List Summary Report*

QI = Qualified Investigator, PCRA = Principal Clinical Research Associate, ECRA = Ethics Clinical Research Associate, PPHARM = Principal Pharmacist, SI = Sub-Investigator, ACRA = Additional Clinical Research Associate, PHARM = Pharmacist, PTECH = Pharmacy Technician

1 = Confirm Subject Eligibility, 2 = Informed Consent, 3 = Trial-Related Medical Decisions, 6 = Request/Coordinate Unblinding, 10 = IRB/REB Communication, 11 = Pre-Trial Subject Screening, 14 = Processing Subject Enrolment, 15 = Accountability of Investigational Agent(s), 16 = Dispensing of Investigational Agent(s), 17 = Administration of Investigational Agent(s), 19 = Perform Medical Assessments Required for Trial, 20 = Perform Other Assessments, 21 = Data Management, 22 = Biologic Sample Management, 23 = Document Adverse Events, Other = Other, specify

Date Generated: [Date that the report is generated in RIPPLE]
Version 1.0

10 APPENDIX III – Participants List (Detailed) Report

Participants List for Trial [Code] (Detailed)
Trial title according to the protocol.

Centre Code: [Code]
Legal centre name according to the Centre Agreement (Maintained by CCTG).

Qualified Investigator

Name	Effective Dates	
	Start	Stop
Lists currently active (and any ever active) QIs. Name displays as Last Name, First Name Ordered descending based on Effective Start Date	Effective start date [YYYY-MON-DD]	Effective stop date [YYYY-MON-DD]

Remote Roster Administrators (can create and edit PLs in RIPPLE)

Name
Lists all active RRAs
Name displays as Last Name, First Name

Participants List Delegate (can edit and approve PLs in RIPPLE)

Name	Addition Approval		Removal Approval		Effective Dates for Delegation	
	Date		Date		Start	Stop
Lists all ever PLDs Name displays as Last Name, First Name Ordered descending based on Effective Start Date	Date of QI approval of PLD addition [YYYY-MON-DD]		Date of QI approval of PLD removal [YYYY-MON-DD]		Effective start date [YYYY-MON-DD]	Effective stop date [YYYY-MON-DD]

Participants List Administrator(s) (can create and edit PLs in RIPPLE)

Name	Effective Dates	
	Start	Stop
Lists all ever PLAs Name displays as Last Name, First Name Ordered descending based on Effective Start Date	Effective start date [YYYY-MON-DD]	Effective stop date [YYYY-MON-DD]

Participants List and Delegation of Trial Related Duties (Active)

Name	Role and Duties	Requested Dates for Delegation		Date Submitted for Approval	Date Requirements Met	Addition Approval		Removal Approval		Effective Dates for Delegation	
		Start	Stop			By	Date	By	Date	Start	Stop
Lists all active Participants on the PL Name displays as Last Name, First Name Ordered by Effective Start Date and role (Essential Roles then Other Roles) If no active participants then No active participants is displayed	Duties appear based on duties delegated in the trial PL Ordered by Duty #. If there is an 'Other' Duty then Specify appears with the duty listed.	Requested start date [YYYY-MON-DD]	Requested stop date [YYYY-MON-DD]	Date that the role was added to the trial PL [YYYY-MON-DD]	The date the participant met all training and credentialing requirements for the trial [YYYY-MON-DD]	Name of person who approved the addition (First/Middle/Last Name)	Date of approval [YYYY-MON-DD]	Name of person who approved the removal (First/Middle Last Name)	Date of approval [YYYY-MON-DD]	Effective start date [YYYY-MON-DD]	Effective stop date [YYYY-MON-DD]

Note: the **Pending** and **Removed** sections for **Participants List and Delegation of Trial Related Duties** are consistent with the **Active** section above

Role and Delegated Duty Description

QI = Qualified Investigator, PCRA = Principal Clinical Research Associate, ECRA = Ethics Clinical Research Associate, PPHARM = Principal Pharmacist, SI = Sub-Investigator, ACRA = Additional Clinical Research Associate, PHARM = Pharmacist, PTECH = Pharmacy Technician, 1 = Confirm Subject Eligibility, 2 = Informed Consent, 3 = Trial-Related Medical Decisions, 6 = Request/Coordinate Unblinding, 10 = IRB/REB Communication, 11 = Pre-Trial Subject Screening, 14 = Processing Subject Enrolment, 15 = Accountability of Investigational Agent(s), 16 = Dispensing of Investigational Agent(s), 17 = Administration of Investigational Agent(s), 19 = Perform Medical Assessments Required for Trial, 20 = Perform Other Assessments, 21 = Data Management, 22 = Biologic Sample Management, 23 = Document Adverse Events, Other = Other, specify

Date Generated: [Date that the report is generated in RIPPLE]

11 APPENDIX IV – Training & Credentialing Report

Training & Credentialing Report for Trial [Code]
Trial Title according to protocol
Trial Complexity level (Maintained by CCTG)
This report shows the most recent dates of submission for each column.

Centre Code: [Code]
Legal centre name according to the centre agreement
(Maintained by CCTG)

Investigators

Name & Role	Training					Credentialing		Other
	GCP	Division 5	NIH Training	Site Training	ICT	CV	Requirements
Lists all GIs and SIs. Name displays as Last Name, First Name with Role and Effective Start Date (and Stop date if applicable) Ordered descending based on Effective Start Date If pending then (Pending) will appear beside role and Effective Dates Not Available If active then [YYYY-MON-DD] to present (or [YYYY-MON-DD] if there is an effective stop date) appears If removed then (Removed) will appear beside role If removed but was once active then (Removed) appears beside the role and [YYYY-MON-DD] to [YYYY-MON-DD] appears If removed but was never active then (removed) appears beside role and [Never effective, removed on [YYYY-MON-DD] appears	All GCP modules are listed separately If completed then the most recently completed version appears with the module name and the date of completion [YYYY-MON-DD] If not completed but required then Required appears If not completed but not required then NA appears	If completed then the completion date appears as [YYYY-MON-DD] If not completed but required then Required appears If not completed but not required then NA appears	If completed then the completion date appears as [YYYY-MON-DD] If not completed but required then Required appears If not completed but not required then NA appears	If completed then the most recent completed version appears with module name and date of completion [YYYY-MON-DD] If not completed but required then Required appears If not completed but not required then NA appears	ICT is assigned by CCTG upon CV review & approval TYPE1, TYPE2, or TYPE3 will appear here based on the latest (approved) CV submission Required appears when the investigator does not have an approved CV	Date of latest (approved) CV submission [YYYY-MON-DD] If there is no date then there is no approved CV	All other requirements are listed as applicable for the role Requirements using document uploads will appear as [Doc Acronym]: [YYYY-MON-DD] or Completed or Required If a document is uploaded but not yet approved then Completed appears If a document is not uploaded but required then Required appears

GI = Qualified Investigator, PCRA = Principal Clinical Research Associate, ECRA = Ethics Clinical Research Associate, PPHARM = Principal Pharmacist, SI = Sub-Investigator, ACRA = Additional Clinical Research Associate, PHARM = Pharmacist, PTECH = Pharmacy Technician, CV = Curriculum Vitae, FD = Financial Disclosure, GCP = Good Clinical Practice, ICT = Investigator Credentialing Type, PSF = Participant Signature Form, QIU = Qualified Investigator Undertaking, SAD = Study Acknowledgement/Disclosure, NA = Not Applicable for this Trial
For more information on Trial Complexity Level and ICT refer to the CCTG Investigator Credentialing Policy

Participants Training and Credentials List | Trial: [Code] Centre: [Code] Page 1 of 2

Date Generated: [Date that the report is generated in RIPPLE]
Version 1.1