

CCTG

**RIPPLE USER GUIDE FOR INTERNATIONAL
SITES PARTICIPATING THROUGH A
COOPERATIVE GROUP OR OTHER
ORGANIZATION**

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1 INTRODUCTION

The Roster Interface Program & Participants List Environment (RIPPLE) is a web-based utility where individuals 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, RIPPLE Monitor)
- 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 **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

RRM: Remote Roster Management (in Mango)

STU: Site Training Utility

TSR: Trial Signature Report

3 MEMBERSHIP ACCOUNTS

Individuals at a participating or collaborating group or organization (for example a trial coordinator or monitor) should consult the Remote Roster Management (RRM) Reference Manual for information about obtaining membership accounts, assigning trial roles and obtaining access to CCTG systems.

Individuals at centres participating on the trial (for example individuals performing trial related duties or maintaining the membership roster or trial participants list at their centre) register for a membership account in the RIPPLE system. The membership registration details outlined in this manual refer to Centre members only. This includes the Remote Roster Administrator (RRA) for a centre.

IMPORTANT: Individuals cannot be added to RIPPLE (membership roster component or trial Participants List) until your site/centre has been added to the trial by your coordinating/collaborating group or organization through the Mango system. Please contact your group to confirm this has been completed prior to starting RIPPLE activities.

Please refer to Appendix I (RIPPLE Roles Summary) for details of access to the RIPPLE system.

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 refer to [Appendix I](#) for a table that summarizes all of the RIPPLE roles.

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

3.1.1 Assigning an RRA

- Complete the **Remote Roster Administrator (RRA) Designation Form** for the study. This form is available on the Resources section in RIPPLE or can be obtained from your coordinating/collaborating group for the trial.
- Complete and follow the submission instructions at the bottom of the form (Note: the Designation Form must be signed by your Centre Representative/Qualified Investigator as well as your group)
- In addition to submitting the RRA Designation Form the individual must register a new CCTG Membership Account in RIPPLE.

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 as applicable. 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 Centre 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

A centre member's registration 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**

▼ **New Account Request: wer wert (Approved)**

Approve Reject Hold

Name	<input type="text" value="▼"/>	First* wer	Middle <input type="text"/>	Last* wert
Account User ID*	<input type="text" value="wwert"/>			
Email*	<input type="text" value="wertwer@asdrt.com"/>			

- 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!
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 please
send an email to edc\_activations@ctg.queensu.ca indicating your trial
code, centre code, and role on the study.
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 RIPPLE. Access to other website/utilities will be granted as applicable.

3.3 Information contained in 'My Member Account'

To access 'My Member Account':

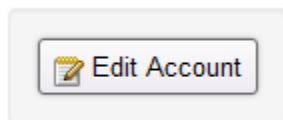
- Log in to RIPPLE using the username and password you created.
- Click or hover over **My Member Account** in the toolbar. Five options will appear that will allow you to manage your account (**Account Information**, **Centre Affiliations**, **My Trials & Roles**, **Uploads**, and **Password Management**):

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) only if it has been completed through one of the CCTG utilities (generally used by Canadian sites only), as well as links to generic applicable training modules and documents. Where credentialing/training information (generally done for international participants) is being collected through document uploads on the trial participants list these tables will be empty. By clicking on the appropriate links the member will be able to access the required document to be completed (e.g. Participant Signature Form). Please refer to section 3.3.2 for details on uploading generic training/credentialing documents and confirm what is required by the participating or coordinating group or organization for the trial on which you are participating

3.3.2 Uploads

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

Generic Uploads can be done by the member or by the site RRA. Trial specific documents are uploaded/completed in a different manner. Please refer to section 7.9.2 for details and liaise with the participating or coordinating group or organization for the trial on which you are participating regarding what is required. **For most members participating on these trials, the only generic upload to the membership account will be the Participant Signature Form. All other training/credentialing requirements will be trial specific and will be collected on the trial Participants List.**

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

My Upload History - Ethil Cra

Show Instructions

Submit: Participant Signature Form

Search Report

Search Clear

First | Prev | 1 | Next | Last

Record Count: 1

#	Upload ID	Upload Date	Upload Time	Document Type	Filename	Comments	Comment Date	Actions
1	402167	2015-AUG-17	02:15 PM	signature	EthilCra_cropped.jpg			Open

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

Save, Print, Sign and Scan PSF

1. **Print** the **Canadian Cancer Trials Group Participant Signature Form (PSF)**
2. **Complete** the physical copy by legibly printing your **Name** and **Initials**, and by signing your **Signature** on the lines indicated.
3. **Scan** the signed document to produce the image to upload to Central Office.
If you need assistance during this step, please contact your local IT department. Printing and scanning processes will vary depending on your institution's set up and specific devices. If you are unable to scan your Signature Document, you will have to mail your completed physical copy of the Signature Document to Central Office.

Tips:

- Ensure the rectangular box is the **ONLY** thing on the page when scanned & uploaded
- The scanned image must be a JPEG or PNG file.
- The maximum file size for uploads is **50MB**.
- Your initials, name and signature must be clearly legible in the scanned image of the document.
- Do not make alterations to the document.

Upload Completed Signature Document

Only file types: pdf, jpg, jpeg, png

Choose File No file chosen

- 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

 Your signature document was successfully uploaded to Central Office.

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

First | Prev | 1 | Next | Last Record Count: 1

#	Upload ID	Upload Date	Upload Time	Document Type	Filename	Comments	Comment Date	Actions
1	402167	2015-AUG-17	02:15 PM	signature	EthilCra_cropped.jpg			Open

There are two reports available that document all of the uploads that have been received or are outstanding for a trial at a centre. They are the **Document Upload Summary** and **Document Upload Detailed** reports and they are located under the **Reports** section of the Participants List for a trial. These reports may be run by the QI, RRA, PLA or PLD for the trial at the site or the RIPPLE Monitor at the group. Please refer to section 7.14 for more detailed information on these reports

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 centre participating on a CCTG trial.

Centres - Remo Ross Admin

[Register with an Additional Centre](#)

Centre Affiliations

CAZZ - The Ripple Institute of Eastern
Ontario
123 Fake Street
Kingston, ON, Canada
K7L 3N6
(613) 533-6000

[Transfer/Remove Roles](#)

[Remove Affiliation](#)

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**

[Register with an Additional Centre](#)

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

Register with an Additional Centre

Centre

[Cancel](#)


[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**

Remove Centre Affiliation - Remo Ross Admin

Confirm Removal

Removal Effective Date *

 Select the date to remove

2015NOV06 

[Cancel](#)

[Submit](#)

Important: This should only be done if the individual is leaving the centre and not just leaving this specific study.

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 participating 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. This should only be done if the individual will no longer be participating on any CCTG trials at the centre.

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. 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.

The Password Management Utility can only be accessed 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 access to 'My Member Account' information

Account information can be viewed and updated by the member, the monitor (view only) for the trial, 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) 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 to become active on a Trial PL in RIPPLE.

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. To view a list of uploaded and/or outstanding PSFs for a particular trial please refer to the Document Upload Summary and/or Document Upload Detailed reports available under the Reports section of the Participants List.

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. PSFs are an activation requirement for all roles assigned to RIPPLE Trial Participants Lists.

5 MEMBER ACCOUNT SUMMARIES IN RIPPLE

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)

[Home](#) / [Administration](#) / Centre Members - CAZZ

Centre Members - CAZZ

Centre: CAZZ - The Ripple Institute of Eastern Ontario, Kingston ON

All Members | Investigators | Clinical Trial Personnel

Include inactive/removed members?

Mrs. A.C.N. Practitioner	Ms. C.R.A. Noncompliant	Dr. Genny Practitioner
Mrs. Addy Cra	Ms. Connie Cra	Mr. Helpy McHelperson
Dr. Addy Investigator	Mr. Demo Pharma	Dr. Iam Noncompliant
Dr. Alan Smithee	Ms. Ethil Cra	Mrs. Jane Doe

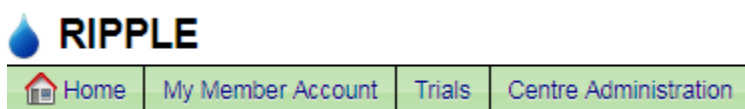
Clicking on an individual member will direct to that individuals account.

6 RIPPLE ROLES

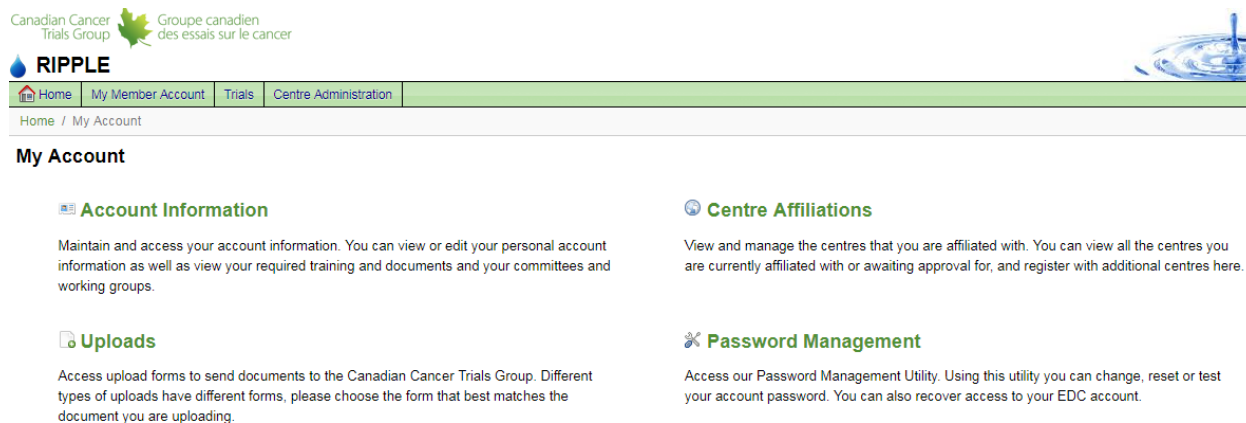
6.1 Assigning RIPPLE roles

RIPPLE roles include the RIPPLE Monitor, 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 submission of the RRA Designation Form. 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.



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

RIPPLE

Home / My Account

My Account

Account Information

Maintain and access your account information. You can view or edit your personal account information as well as view your required training and documents and your committees and working groups.

Centre Affiliations

View and manage the centres that you are affiliated with. You can view all the centres you are currently affiliated with or awaiting approval for, and register with additional centres here.

Uploads

Access upload forms to send documents to the Canadian Cancer Trials Group. Different types of uploads have different forms, please choose the form that best matches the document you are uploading.

Password Management

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

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.

Important: PLAs, PLDs and RRAs should only assign RIPPLE roles for trials to which they have been assigned or are affiliated with.

6.2 RIPPLE Monitor

RIPPLE Monitors are individuals at the participating or collaborating group or organization not at individual sites. RIPPLE monitors have read only access to the membership accounts and trial participants lists for the centres/members in their region only for their assigned trial(s). Monitors are not able to upload credentialing/training documents but are able to view and download these documents as required. Individuals at the group/organization are assigned the RIPPLE Monitor role when they are

added to Remote Roster Management in specific regional roles (e.g. external monitor or Group RRA) for the trial. The RIPPLE Monitor is not assigned in RIPPLE and cannot be assigned to centre members.

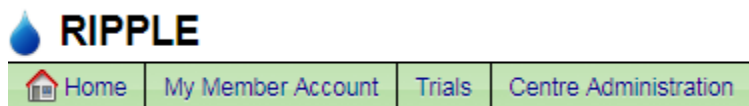
6.3 Participants List Administrator

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 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.

6.3.1 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
- Select the name of the PLA from the drop down list which includes all active Members at the centre

Add New Role

Role

Trial

Member

- 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

Current Roles

Name	Trial	Role	Role Status	Assignment Date	Removal Date	Remove
Ms. Elle Elephant	CE8	PLA - Participants List Administrator	Active	2019-MAR-27		<input type="checkbox"/>

- 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

6.3.2 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

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	<input type="checkbox"/>
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

Remove Selected

- 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

6.4 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. Centres should liaise with the partner/collaborator/group responsible for their oversight to ensure their local SOPs are appropriate and permit this delegation for this specific trial.

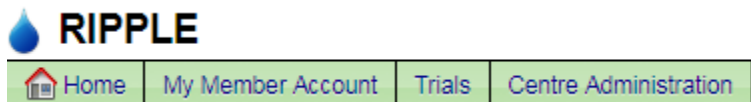
The PLD role is **optional**. There can only be 1 PLD per trial at each centre. A PLD can modify PLs and CAN approve all PL changes, whereas an RRA and PLA can create/modify PLs but CANNOT approve PL changes.

6.4.1 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) and in consultation with the coordinating or participating group or organization. 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.

6.4.2 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

Add New Role

Role

Trial

Member

- Select **Submit**

6.4.3 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

PLD Decision Required

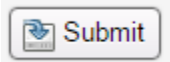
- The Batch Approvals page appears with the pending PLD decision.

Centre	Trial	QI Approval?	Action
CAZZ	CEC5	Pending	<p>Do you accept being a PLD on this trial?</p> <p> <input type="radio"/> Accept <input type="radio"/> Reject <input checked="" type="radio"/> Hold </p>

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

Action
Do you accept being a PLD on this trial?
<input checked="" type="radio"/> Accept <input type="radio"/> Reject <input type="radio"/> Hold

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



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



- For trials for which the PLD assignment was accepted once the participant is approved by the QI they can start performing PLD duties

6.4.4 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	<input type="checkbox"/>
--------------------------	------	--	---------------------	-----------------	--	--	--	---------	-----	--------------------------

- 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	Participation Status	Issues/Comments	Action
CAZZ	SAR06	Remo Ross Admin	PLD	not applicable	2015-OCT-23		Initial Approval <input checked="" type="radio"/> Approve <input type="radio"/> Reject <input type="radio"/> 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	<input type="checkbox"/>
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 \(PLD\)](#)

6.4.5 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. Testy McTesterson	MA32	PLD - Participants List Delegate	Active	2017-SEP-05		n/a		2017-SEP-11	n/a	<input checked="" type="checkbox"/>

- Select **Remove Selected**

Remove Selected

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

Confirm Remove ✕

Please confirm that you want to remove the selected roles.

Note: Removal of any active Participants List Delegate (PLD) role must be approved by the trial QI before it will be removed.

Click **Confirm** or **Cancel** to go back to the form and review before submitting.

- 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	Participation Status	Issues/Comments	Action
CAZZ	SAR06	Remo Ross Admin	PLD	not applicable	2015-OCT-23	2015-OCT-23	Approve All Initial Approval 2015-OCT-23 Stop Approval <input checked="" type="radio"/> Acknowledge <input type="radio"/> 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.

6.4.6 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.

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

6.5 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. 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 and RIPPLE Monitors.
 - 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	MA32	PLA - Participants List Administrator	Active	2018-SEP-26		n/a	n/a	n/a	n/a	<input type="checkbox"/>
Mr. Testy McTesterson	MA32	PLD - Participants List Delegate	Active	2017-SEP-05		n/a		2017-SEP-11	n/a	<input type="checkbox"/>
Mr. Helpy McHelperson	n/a	RRA - Remote Roster Administrator	Active	2014-DEC-11		n/a	n/a	n/a	n/a	n/a

2. 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

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)

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

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 University



Qualified Investigator

Name	Effective Dates	
	Start	Stop
Investigator, Quaili	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
RIPPLE Monitor	No	No	No

7.2 How to Access a Trial Participants List

After signing in to RIPPLE a participant will be taken to their centre homepage.

The tabs on the homepage cover the applicable 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 participants list if applicable.

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 Requirements

Requirements / Roles	QI	PCRA	ECRA	PPHARM	SI	ACRA	PHARM	PTECH	Duty 1	Duty 3
Study Acknowledgement/Disclosure	🚩	○	○	○	○	○	○	○		
Financial Disclosure Form	🚩	○	○	○	🚩	○	○	○		
Form FDA 1572	🚩	○	○	○	○	○	○	○		
Curriculum Vitae	🚩	○	○	○	🚩	○	○	○		
Protocol Training	🚩	🚩	🚩	🚩	🚩	🚩	🚩	🚩		
GCP Training	🚩	🚩	🚩	🚩	🚩	🚩	🚩	🚩		
Participant Signature Form	🚩	🚩	🚩	🚩	🚩	🚩	🚩	🚩		

🚩 = Required, click to submit/upload

Complexity Description
Level 2: Standard Risk and Complexity; Trials that test an oncologic-directed medical intervention (e.g., a drug, radiation therapy, surgical technique).

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 by uploading the specific document. Clicking on the required icon allows a participant to upload any outstanding documents (Please refer to section 7.9 - Credentialing and Training for detailed instructions).

Trial Complexity Level: 2
Trial Status: Open to Accrual
Lead Group: **Lead Group Trial Code:**
Trial Under CTA: Yes, Trial Affiliated With NCTN: No

Centre:

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. Quentin Quail	QI	1, 2, 3, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23	2019-MAY-15	2019-MAY-15			Initial	Active		Details
Mr. Porky Pig	PCRA	2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23	2019-MAY-15	2019-MAY-15			Initial	Active		Details
Mr. Ronald Rooster	ECRA	10	2019-MAY-15	2019-MAY-15			Initial	Active		Details
Ms. Sissy Seal	PPHARM	15, 16	2019-MAY-15	2019-MAY-15			Initial	Active		Details
Mr. Tony Tiger	SI	1, 2, 3, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23	2019-MAY-15	2019-MAY-15			Initial	Active		Details
Ms. Sissy Seal	ECRA	10	2019-MAY-29				None	Pending	QI approval required	Details/Edit
Mr. Ronald Rooster	SI	1, 2, 3, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23	2019-MAY-29				None	Pending	Requirements not met	Details/Edit
Mr. Tony Tiger	ACRA	2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23	2019-MAY-29				None	Pending	QI approval required	Details/Edit

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

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

Required Roles Met
All trial related duties can be performed by their delegates

Req. roles active since: 2019-MAY-15

Required Roles

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

Reports

- [Participants List \(Summary\)](#)
- [Participants List \(Detailed\)](#)
- [Trial Signature Report](#)
- [Document Upload Summary](#)
- [Document Upload Detailed](#)

Data Management

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

Edit PL & Approve Changes
Dr. Quentin Quail (QI)

Edit PL
Mr. Porky Pig (RRA)
Ms. Sissy Seal (PLA)

[Hide Sidebar](#)

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 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

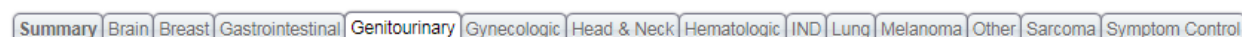
Reminder: Only an RRA or a PLA assigned to that trial can create an initial PL for a trial

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



Home / Trials - CAZZ / View Trials

- Locate the applicable trial by selecting the **disease site** from the tabs and choosing the appropriate trial. The options on the tab will vary depending on what trials your site is participating on
















- 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:

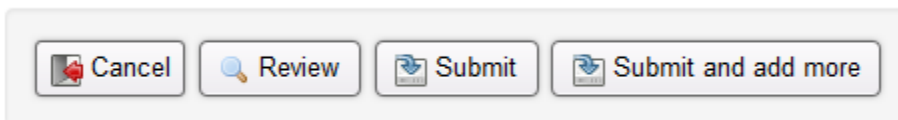
https://www.ctg.queensu.ca/trials/generic_forms/PL_PLCF/pl_plcf_requirements.html

Centre: CAZZ				
The Ripple Institute of Eastern Ontario				
Name *	Role *	Duties * 	Requested Start Date *	Requested Stop Date
-->	QI	1 2 3 6 10 11 14 15 16 17 19 20 21 22 23 <input type="checkbox"/> Other 	2015OCT21 	
-->	PCRA	<input checked="" type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input checked="" type="checkbox"/> 3 <input checked="" type="checkbox"/> 6 <input checked="" type="checkbox"/> 10 <input checked="" type="checkbox"/> 11 <input checked="" type="checkbox"/> 14 <input checked="" type="checkbox"/> 15 <input checked="" type="checkbox"/> 16 <input checked="" type="checkbox"/> 17 <input checked="" type="checkbox"/> 19 <input checked="" type="checkbox"/> 20 <input checked="" type="checkbox"/> 21 <input checked="" type="checkbox"/> 22 <input checked="" type="checkbox"/> 23 <input type="checkbox"/> Other 	2015OCT21 	
-->	ECRA	1 2 3 6 10 11 14 15 16 17 19 20 21 22 23 <input type="checkbox"/> Other 	2015OCT21 	
-->	PPHARM	1 2 3 6 10 11 14 <input checked="" type="checkbox"/> 15 <input checked="" type="checkbox"/> 16 17 19 20 21 22 23 <input type="checkbox"/> Other 	2015OCT21 	
Add another participant				

- 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.

[View Trials](#)

[Show Instructions](#)

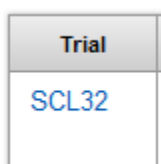
CAZZ - The Ripple Institute of Eastern Ontario

Summary Brain Breast Gastrointestinal Genitourinary Gynecologic Hematologic IND Lung Melanoma Sarcoma Symptom Control

Participating Trials - View Participants List

Trial	Trial Title	Participation	Trial Status	Requirements
SCL32	A Randomized Phase II Trial of Maintenance Therapy With Treatment or Placebo in Patients with Small Cell Lung Cancer	Open to member centres	Open to Accrual	List/Submit

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



- o Selecting **Details/Edit** under the **Action** column will show the date the QI/PLD approved the addition

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
SCL32	CAZZ	Mr Prince Cra	PCRA	2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23	2015-SEP-18	2015-SEP-18	2015-SEP-18	2015-SEP-18				Active	

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

Name	Role	Delegated Duties	Requested Start Date	Effective Start Date	Requested Stop Date	Effective Stop Date	Approval	Participation Status	Issues/Comments	Action
Mr. Prince Cra	PCRA	2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23	2015-SEP-18	2015-SEP-18			Initial	Active		Details

3. The requested start date has been met

Once all three 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 three criteria are NOT met then the **Participation Status** on the Trial PL will remain as **Pending**

Participation Status
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**.
 - o 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**.

Issues/Comments
Requirements not met

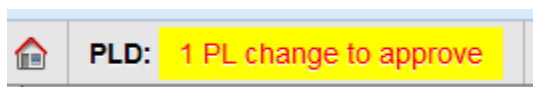
- o Selecting **details** in the **Action** column will show that the **Date Requirements Met** column is empty. Below the table it will specify which of the requirements have not been met and will also include the required action and resolution.
- o The Participant will also automatically receive an 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
- o 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:

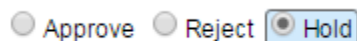
- Either sign in to RIPPLE directly or click on the RIPPLE link in the email notification they receive. They can then sign in to RIPPLE using their CCTG user ID and password
- At the top left of the QIs/PLDs main page the tool bar will indicate if there are any changes to approve and how many there are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



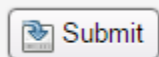
- The QI can click on the link in the tool bar to access the QI/PLD approval page
- All PL changes (additions and removals) for all trials the QI/PLD is assigned to will appear on a single page

Centre	Trial Code	Name	Role	Delegated Duties [®]	Requested Start Date	Requested Stop Date	Approval	Participation Status	Issues/Comments	Action
CAZZ	MA36	Jane Doe	PLD	not applicable	2015-NOV-02		Approve All Initial Approval <input type="radio"/> Approve <input type="radio"/> Reject <input checked="" type="radio"/> Hold	Pending Approval	QI approval required	
CAZZ	SAR06	Remo Ross Admin	PLD	not applicable	2015-OCT-23	2015-OCT-23	Initial Approval 2015-OCT-23 Stop Approval <input type="radio"/> Acknowledge <input checked="" type="radio"/> Hold		QI approval required	
CAZZ	SCL32	Addy Cra	ACRA	2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23 *	2015-SEP-18	2015-OCT-05	Initial Approval 2015-SEP-18 Stop Approval <input type="radio"/> Approve <input type="radio"/> Reject <input checked="" type="radio"/> Hold	Active	Removal approval required	View PL

- 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

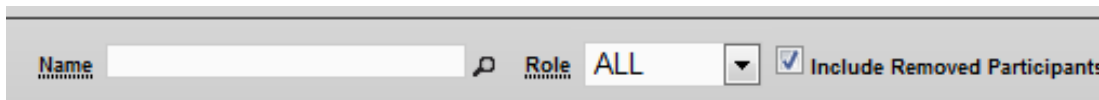
- The participant status will also change to **Active** if it is an addition and **Removed** if it is a removal.

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). A Participant Signature Form is an example of a standard requirement.
- 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. These requirements are usually satisfied with document uploads in the trial Participants List. Some examples of this include
 - Investigator CVs
 - GCP
 - Protocol training
 - Financial Disclosure Form
 - Study Acknowledgement/Disclosure Form
 - Form FDA 1572

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 and the monitor at the site can also view the 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 Requirements										
Requirements / Roles	QI	PCRA	ECRA	PPHARM	SI	ACRA	PHARM	PTECH	Duty 1	Duty 3
Study Acknowledgement/Disclosure		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
Financial Disclosure Form		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
Form FDA 1572		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
Curriculum Vitae		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
Protocol Training										
GCP Training										
Participant Signature Form										
= Required, click to submit/upload										
Complexity Description Level 2: Standard Risk and Complexity; Trials that test an oncologic-directed medical intervention (e.g., a drug, radiation therapy, surgical technique).										
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										

Note: For trials which require a Form FDA 1572 the form is required to include the QI and all SIs, however, it is only uploaded to the QI's PL record for a trial. When a new SI/QI is added to the PL over the course of the trial, an amended 1572 form should always be uploaded to the QI account including the new SI(s)/QI being added to RIPPLE.

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

Uploading documents


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



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

Member

Document to Upload*

 Only file types: pdf, jpg, jpeg, png

Choose File No file chosen

Document Type*

Study Acknowledgement/Disclosure

Comments/Notes


Cancel Upload

- 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

 Study Acknowledgement/Disclosure successfully uploaded 

Member

Document to Upload*

 Only file types: pdf, jpg, jpeg, png

Choose File No file chosen

Document Type*

Study Acknowledgement/Disclosure

Comments/Notes

Cancel Upload

First | Prev | 1 | Next | Last

Record Count: 1

#	Upload Date	Member	Document	Comments	Actions
1	2018-OCT-22		Study Acknowledgement/Disclosure		Open

- **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

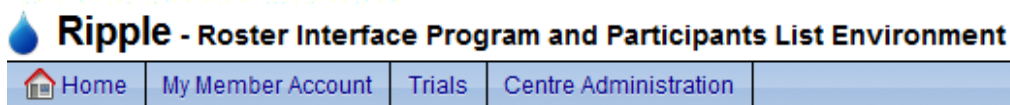
- If the participant has been added to the trial PL and they do not have all credentialing/training required for that role on that trial it will indicate **requirements not met**
- Click on **Details/Edit** in the right hand column of the participant entry.

Dr. Iam Noncompliant	SI	1, 2, 3, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23	2015-AUG-31				Initial	Pending	Requirements not met	Details/Edit
-------------------------	----	---	-------------	--	--	--	---------	---------	----------------------	--------------

- 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 upload the missing document
- Select this link (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)

7.9.2.1 Member Account

- Members themselves can 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

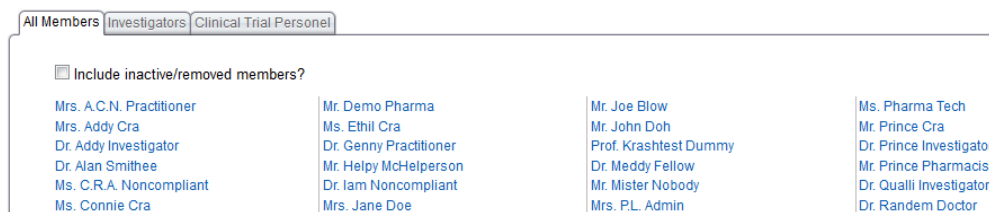
Centre Members

Access a full list of centre members. You can navigate to each member's "My Member Account" page as that user by clicking on their name in the list. This will allow you to perform actions on behalf of the member (such as uploading a signature document).

- Select the participant that has documents to be uploaded

Centre Members - CAZZ

Centre: CAZZ - The Ripple Institute of Eastern Ontario, Kingston ON



All Members | Investigators | Clinical Trial Personnel

Include inactive/removed members?

Mrs. A.C.N. Practitioner	Mr. Demo Pharma	Mr. Joe Blow	Ms. Pharma Tech
Mrs. Addy Cra	Ms. Ethil Cra	Mr. John Doh	Mr. Prince Cra
Dr. Addy Investigator	Dr. Genny Practitioner	Prof. Krashtest Dummy	Dr. Prince Investigator
Dr. Alan Smithie	Mr. Helpy McHelperson	Dr. Meddy Fellow	Mr. Prince Pharmacist
Ms. C.R.A. Noncompliant	Dr. Iam Noncompliant	Mr. Mister Nobody	Dr. Qualli Investigator
Ms. Connie Cra	Mrs. Jane Doe	Mrs. P.L. Admin	Dr. Randem Doctor

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

[✓ View Account](#)

[✕ Close](#)

- Select **Uploads**

Uploads

Access upload forms to send documents to the Canadian Cancer Trials Group. Different types of uploads have different forms, please choose the form that best matches the document you are uploading.

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

My Upload History - Ethil Cra

[Show Instructions](#)

Submit:

Search Report

First | Prev | 1 | Next | Last

Record Count: 1

#	Upload ID	Upload Date	Upload Time	Document Type	Filename	Comments	Comment Date	Actions
1	402167	2015-AUG-17	02:15 PM	signature	EthilCra_cropped.jpg			Open

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


Save, Print, Sign and Scan PSF

1. Print the [Canadian Cancer Trials Group Participant Signature Form \(PSF\)](#)
2. **Complete** the physical copy by legibly printing your **Name** and **Initials**, and by signing your **Signature** on the lines indicated.
3. **Scan** the signed document to produce the image to upload to Central Office.
If you need assistance during this step, please contact your local IT department. Printing and scanning processes will vary depending on your institution's set up and specific devices. If you are unable to scan your Signature Document, you will have to mail your completed physical copy of the Signature Document to Central Office.

Tips:


- Ensure the rectangular box is the **ONLY** thing on the page when scanned & uploaded
- The scanned image must be a JPEG or PNG file.
- The maximum file size for uploads is **50MB**.
- Your initials, name and signature must be clearly legible in the scanned image of the document.
- Do not make alterations to the document.

Upload Completed Signature Document

 Only file types: pdf, jpg, jpeg, png

No file chosen

- 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

 Your signature document was successfully uploaded to Central Office.

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

First | Prev | 1 | Next | Last Record Count: 1

#	Upload ID	Upload Date	Upload Time	Document Type	Filename	Comments	Comment Date	Actions
1	402167	2015-AUG-17	02:15 PM	signature	EthilCra_cropped.jpg			Open

7.9.3 Protocol Training

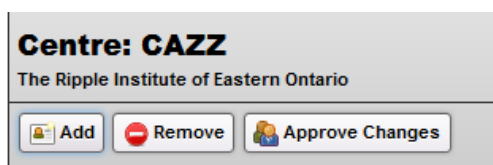
Any protocol training related requirements for a trial will be outlined in the credentialing requirements table for that trial. RIPPLE will check on completion of this training as a component of the **Requirements met** checks to ensure that trial specific protocol training has been completed for each individual for which it is required.

To view a list of all received and outstanding uploads please refer to the Document Upload Summary and Document Upload Detailed reports.

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

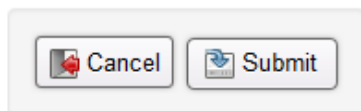


- Enter the appropriate **date** in the **Requested Stop Date** column for the applicable participant/role



Requested Stop Date

- 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**



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.

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.

7.10.2 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**

Options



- 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

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

Centre: CAZZ
 The Ripple Institute of Eastern Ontario Queen's University

Name *	Role *	Duties *	Requested Start Date *	Requested Stop Date																				
<input type="text" value="Demo Pharma"/>	<input type="text"/>	<table style="font-size: small; border-collapse: collapse;"> <tr> <td>1</td><td>2</td><td>3</td><td>6</td><td>10</td></tr> <tr> <td>11</td><td>14</td><td>15</td><td>16</td><td>17</td></tr> <tr> <td>19</td><td>20</td><td>21</td><td>22</td><td>23</td></tr> <tr> <td colspan="5" style="text-align: center;">Other </td> </tr> </table>	1	2	3	6	10	11	14	15	16	17	19	20	21	22	23	Other					<input type="text" value="2016JUN23"/>	<input type="text"/>
1	2	3	6	10																				
11	14	15	16	17																				
19	20	21	22	23																				
Other																								

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

Cancel

Review

Submit

- 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

Centre: CAZZ
 The Ripple Institute of Eastern Ontario

Add

Remove

Approve Changes

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

Requested Stop Date

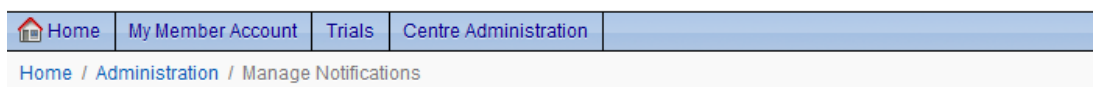
- To enter the updated record follow the same process as adding a new Participant and enter the updated information
- Both the removal and addition will require QI/PLD approval
 - Note that the participant is non-compliant if they start performing their delegated duties prior to QI/PLD approval

- 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. Centres should liaise with the sponsor or coordinating group for any further requirements.

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**.



Manage Notifications

Account Notifications

Manage recipients for Account and Centre related notifications.

Participants List Notifications

Manage recipients for specific notifications. These notifications can be configured for specific trials, or for all trials.

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. **Document upload**- Sent to 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.

7.12.2 Participants List Notifications

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

The following notifications are available:

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
- 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, PLD and PLA can 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.

- 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 should contact the sponsor or coordinating group to determine if printouts of the PL reports or trial signature reports from RIPPLE are required. 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. Participant Signature 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.

Required Roles Met
All trial related duties can be performed by their delegates

Req. roles active since: 2019-MAR-21

Required Roles

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

Reports

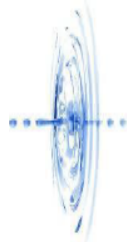
- [Participants List \(Summary\)](#)
- [Participants List \(Detailed\)](#)
- [Trial Signature Report](#)
- [Document Upload Summary](#)
- [Document Upload Detailed](#)

- 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
- 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

- **Document Upload Summary:** This is a trial specific report which provides a list of all documents that have been received or are outstanding for all active, pending and inactive participants on the trial.
- **Document Upload Detailed Reports:** This is a trial specific feature that consists of two components contained within a zip file. The first part contains a detailed list of all uploaded documents for all participants on the selected trial. The second part includes copies of all of the individual uploads for all of the participants on that trial at that centre.

9 APPENDIX II – Participants List (Summary) Report



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

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

Current Qualified Investigator

Effective start and stop dates appear based on the dates entered in the trial PL.	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 <i>Effective dates not available</i> 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 <i>Never effective, removed on [YYYY-MON-DD]</i> 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/ECRAP/PHARM 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 <i>Effective dates not available</i> 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 <i>Never effective, removed on [YYYY-MON-DD]</i> 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

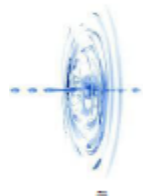
CI = Qualified Investigator, PCRA = Principal Clinical Research Associate, ECRA = Ethics Clinical Research Associate, PPHARM = Principal Pharmacist, SI = Sub-Investigator, ACRA = Additional Clinical Research Associate, PHARM = Pharmacist, PTECH = Pharmacy Technician
1 = Confirm Subject Eligibility, 2 = Informed Consent, 3 = Trial-Related Medical Decisions, 6 = Request/Coordinate Unblinding, 10 = IRB/REB Communication, 11 = Pre-Trial Subject Screening, 14 = Processing Subject Enrollment, 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

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10 APPENDIX III – Participants List (Detailed) Report

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

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



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]

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

Name	Addition Approval		Removal Approval		Effective Dates for Delegation	
	Date	Date	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]	Date of QI approval of PLD removal [YYYY-MON-DD]		Effective start date [YYYY-MON-DD]	Effective stop date [YYYY-MON-DD]

Participants List Administrators (can create and edit PLs in RIPPLE)

Name	Effective Dates	
	Start	Stop
Lists all active RRAs Name displays as Last Name, First Name	Effective start date [YYYY-MON-DD]	Effective stop date [YYYY-MON-DD]

Participants List Administrators (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	
	Duties appear based on duties delegated in the trial PL	Ordered by Duty #	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 [FirstMiddleLast Name]	Name of person who approved the removal [FirstMiddleLast Name]	Effective start date [YYYY-MON-DD]	Effective stop date [YYYY-MON-DD]	Effective start date [YYYY-MON-DD]	Effective stop date [YYYY-MON-DD]		
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	Ordered by Effective Start Date and role (Essential Roles then Other Roles)	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 [FirstMiddleLast Name]	Name of person who approved the removal [FirstMiddleLast Name]	Effective start date [YYYY-MON-DD]	Effective stop date [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 Delegation Duty 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, 1 = Confirm Subject Eligibility, 2 = Informed Consent, 3 = Trial-Related Medical Decisions, 6 = Request/Coordinate Unblinding, 10 = IR/REB Communication, 11 = Pre-Trial Subject Screening, 14 = Processing Subject Enrollment, 15 = Accountability of Investigational Agent(s), 16 = Disposition 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 = Document Adverse Events, Other = Other, specify

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11 APPENDIX IV – Document Upload Summary

	A	B	C	D	E
1	Uploaded	Name	Role	Type	Upload Date
2	N	Rooster, Ronald	SI	Trial Curriculum Vitae	
3	N	Rooster, Ronald	SI	Trial Financial Disclosure Form	
4	Y	Pig, Porky	PCRA	Participant Signature Form (PSF)	15-May-19
5	Y	Pig, Porky	PCRA	Trial GCP Training	15-May-19
6	Y	Pig, Porky	PCRA	Trial Protocol Training	15-May-19
7	Y	Quail, Quentin	QI	Participant Signature Form (PSF)	15-May-19
8	Y	Quail, Quentin	QI	Trial Curriculum Vitae	15-May-19
9	Y	Quail, Quentin	QI	Trial Financial Disclosure Form	15-May-19
10	Y	Quail, Quentin	QI	Trial Form FDA 1572	15-May-19
11	Y	Quail, Quentin	QI	Trial GCP Training	15-May-19
12	Y	Quail, Quentin	QI	Trial Protocol Training	15-May-19
13	Y	Quail, Quentin	QI	Trial Study Acknowledgement/Disclosur	15-May-19
14	Y	Rooster, Ronald	ECRA	Participant Signature Form (PSF)	15-May-19
15	Y	Rooster, Ronald	ECRA	Trial GCP Training	15-May-19
16	Y	Rooster, Ronald	ECRA	Trial Protocol Training	15-May-19
17	Y	Rooster, Ronald	SI	Participant Signature Form (PSF)	15-May-19
18	Y	Rooster, Ronald	SI	Trial GCP Training	15-May-19
19	Y	Rooster, Ronald	SI	Trial Protocol Training	15-May-19
20	Y	Seal, Sissy	ECRA	Participant Signature Form (PSF)	15-May-19
21	Y	Seal, Sissy	ECRA	Trial GCP Training	15-May-19
22	Y	Seal, Sissy	ECRA	Trial Protocol Training	15-May-19
23	Y	Seal, Sissy	PPHARM	Participant Signature Form (PSF)	15-May-19
24	Y	Seal, Sissy	PPHARM	Trial GCP Training	15-May-19
25	Y	Seal, Sissy	PPHARM	Trial Protocol Training	15-May-19
26	Y	Tiger, Tony	ACRA	Participant Signature Form (PSF)	15-May-19
27	Y	Tiger, Tony	ACRA	Trial Curriculum Vitae	15-May-19
28	Y	Tiger, Tony	ACRA	Trial Financial Disclosure Form	15-May-19
29	Y	Tiger, Tony	ACRA	Trial GCP Training	15-May-19
30	Y	Tiger, Tony	ACRA	Trial Protocol Training	15-May-19
31	Y	Tiger, Tony	SI	Participant Signature Form (PSF)	15-May-19
32	Y	Tiger, Tony	SI	Trial Curriculum Vitae	15-May-19
33	Y	Tiger, Tony	SI	Trial Financial Disclosure Form	15-May-19
34	Y	Tiger, Tony	SI	Trial GCP Training	15-May-19
35	Y	Tiger, Tony	SI	Trial Protocol Training	15-May-19