

RIPPLE- Participants List Delegate (PLD)

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Participant List Delegate (PLD)

- The QI can delegate responsibility for approving the delegation of trial related duties in RIPPLE to a PLD
- The PLD must have an active membership account with NCIC CTG and should understand the roles and responsibilities they are delegating
- The PLD can also maintain the delegation list in RIPPLE
- The PLD role is optional and is only applicable to trials in RIPPLE

Participant List Delegate (PLD)

- There can only be 1 PLD per trial at a centre
- The PLD role is assigned in RIPPLE under *Centre Administration > Ripple Roles* and must be approved in RIPPLE by the QI prior to becoming effective
- QIs can still view the complete Participants List at any time in RIPPLE and complete any delegation approvals

Rationale for PLD Role

Initiative to Streamline Clinical Trials (ISCT) report released April 2014:

The delegation list, either the initial list or any modified version, should be created and maintained by the QI, or delegate, in a timely manner....Sign-off of each change to the delegation list by the QI is not required if the task is delegated appropriately.

- <http://n2canada.ca/isct/>
- Reduce QI workload and delays in local PL/delegation approvals

PLD Role – How Is This Different?

| Role | # | Assignment | Member Roster changes/ approvals | Create/ modify PLs | Approve PL changes |
|------|----------|--|----------------------------------|--------------------|--------------------|
| RRA | 2-3 | <ul style="list-style-type: none"> • By centre • Added via RRA form to CTG • Approved by Cen Rep | ✓ | ✓ | X |
| PLD | 1 | <ul style="list-style-type: none"> • Per trial/per centre • Assigned within RIPPLE • Approved by trial QI | X | ✓ | ✓ |
| PLA | No limit | <ul style="list-style-type: none"> • By trial • Assigned within RIPPLE • No approval | X | ✓ | X |

Assigning PLD Role in RIPPLE

Assigning the PLD role:

- Assigned by RRA, PLA or QI in RIPPLE under *Centre Administration > Ripple Roles*
- The QI for trial must approve the PLD in RIPPLE (can be active QI or a pending QI that has met all credentialing/training requirements)
- PLD is not able to approve/delegate roles or make changes to the PL until QI has approved the PLD role
- PLD effective start date = date of QI approval

Removing the PLD role:

- Removed by RRA, PLA or QI in RIPPLE under *Centre Administration > Ripple Roles*
- Removal requires QI approval
- PLD effective stop date = date removed (not date of QI approval)

RIPPLE Notifications

- QI will be notified by email of PLD additions/removals requiring approval
- If a PLD has been approved, the PLD (not the QI) will receive the email for outstanding PL approvals for that trial (sites can manually add the option to ALSO have QI notified in RIPPLE)
- If there is NO PLD approved at that site, the QI will receive the email notifications for outstanding PL approvals for that trial
- When a PLD is removed, the QI will receive a notification that they are now responsible for PL approvals for that trial

Local Policy and QI Oversight

- The ability of the QI to delegate the task of approving the delegation of trial related duties in RIPPLE must be supported by local SOPs.
- Centres must follow their local policy/SOPs for trial delegation and approval
- Determining who is an appropriately qualified individual would be at the discretion of the QI and should be in accordance with local SOP(s).
- The QI remains ultimately responsible for the delegation of significant trial-related duties and ensuring oversight for the conduct of the trial (e.g., training, supervision of trial personnel)

Questions?

ripple@ctg.queensu.ca