RIPPLE – CRA Training

2014APR23

NCIC Clinical Trials Group
NCIC Groupe des essais cliniques

RIPPLE

Roster Interface Program & Participants List Environment

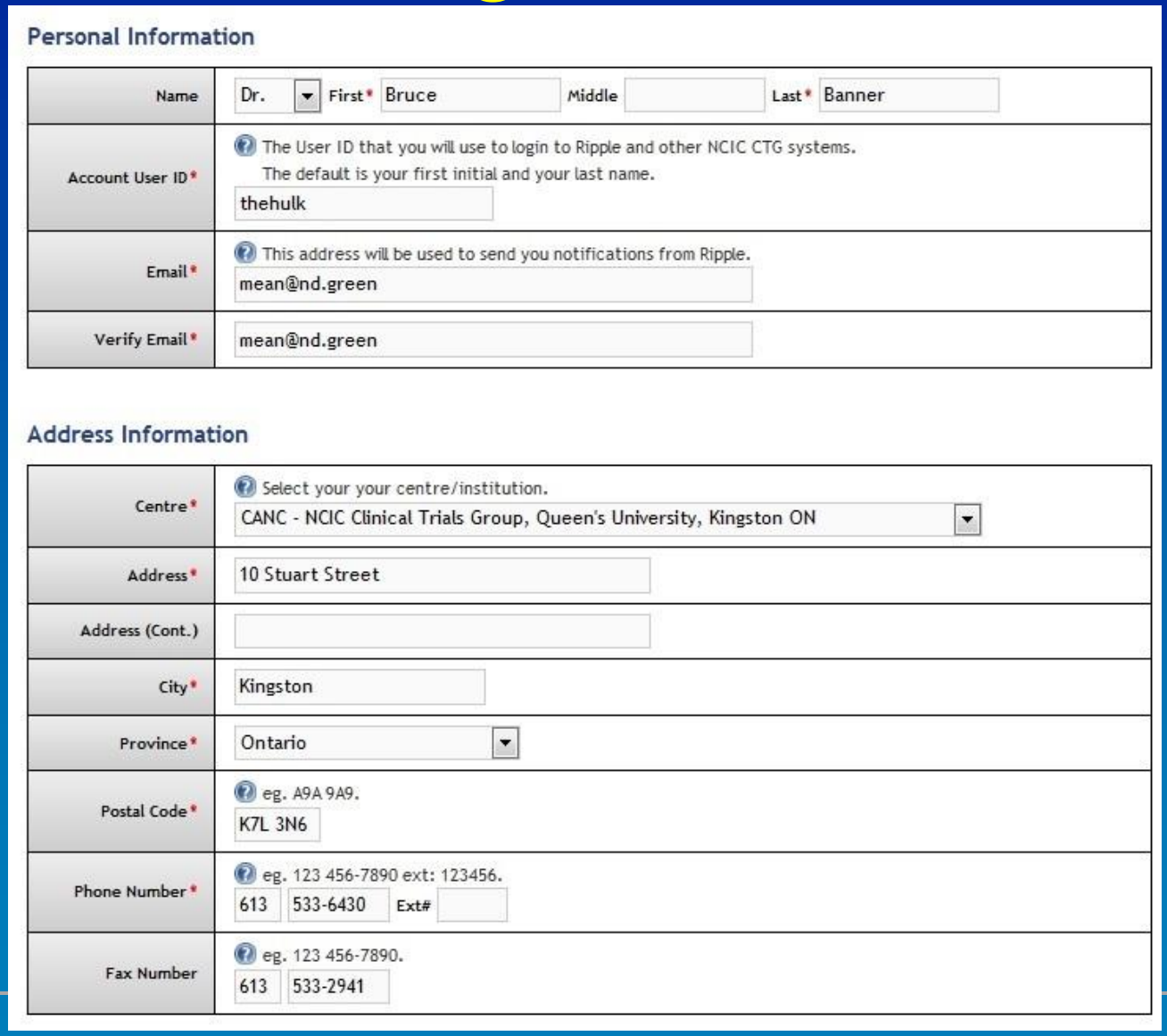
Thanks to the CRAs that assisted over past year with providing feedback from centre perspective and assisted with testing

RIPPLE
Member Registration

Submit account registration electronically

Can be done by Member themselves or by the RRA

RRAs approve new accounts & removal of accounts electronically



Personal Information

Name	Dr. First* Bruce Middle Last* Banner
Account User ID*	The User ID that you will use to login to Ripple and other NCIC CTG systems. The default is your first initial and your last name. thehulk
Email*	This address will be used to send you notifications from Ripple. mean@nd.green
Verify Email*	mean@nd.green

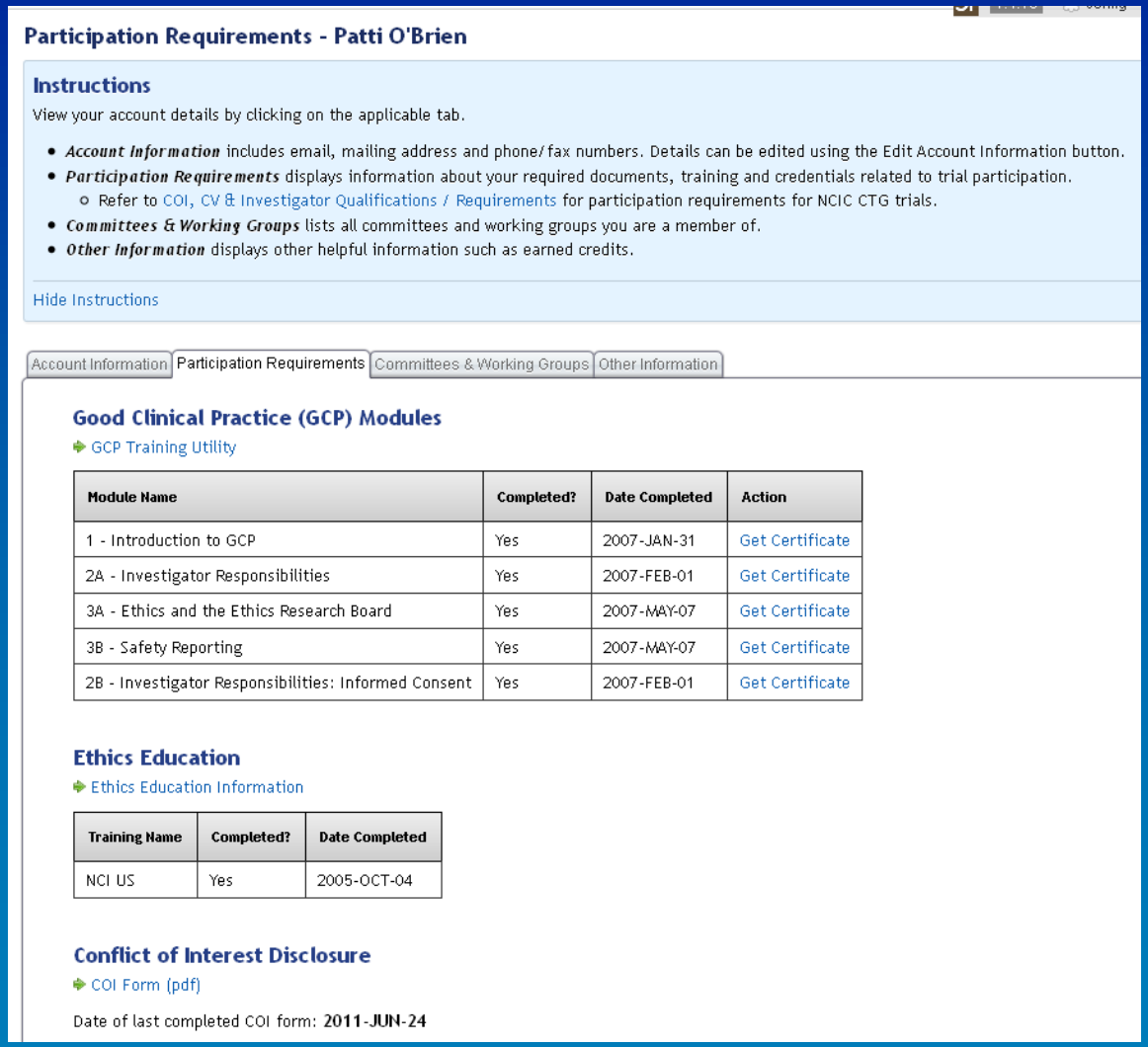
Address Information

Centre*	Select your your centre/institution. CANC - NCIC Clinical Trials Group, Queen's University, Kingston ON
Address*	10 Stuart Street
Address (Cont.)	
City*	Kingston
Province*	Ontario
Postal Code*	eg. A9A 9A9. K7L 3N6
Phone Number*	eg. 123 456-7890 ext: 123456. 613 533-6430 Ext#
Fax Number	eg. 123 456-7890. 613 533-2941

RIPPLE
Participant Training Requirements

Real-time listing of CTG training requirements, including completion status and links to modules

Upload of documents within system such as NIH, Investigator Registration Form and CVs



Participation Requirements - Patti O'Brien

Instructions

View your account details by clicking on the applicable tab.

- ***Account Information*** includes email, mailing address and phone/fax numbers. Details can be edited using the Edit Account Information button.
- ***Participation Requirements*** displays information about your required documents, training and credentials related to trial participation.
  - Refer to COI, CV & Investigator Qualifications / Requirements for participation requirements for NCIC CTG trials.
- ***Committees & Working Groups*** lists all committees and working groups you are a member of.
- ***Other Information*** displays other helpful information such as earned credits.

Hide Instructions

Account Information | Participation Requirements | Committees & Working Groups | Other Information

Good Clinical Practice (GCP) Modules

GCP Training Utility

Module Name	Completed?	Date Completed	Action
1 - Introduction to GCP	Yes	2007-JAN-31	Get Certificate
2A - Investigator Responsibilities	Yes	2007-FEB-01	Get Certificate
3A - Ethics and the Ethics Research Board	Yes	2007-MAY-07	Get Certificate
3B - Safety Reporting	Yes	2007-MAY-07	Get Certificate
2B - Investigator Responsibilities: Informed Consent	Yes	2007-FEB-01	Get Certificate

Ethics Education

Ethics Education Information

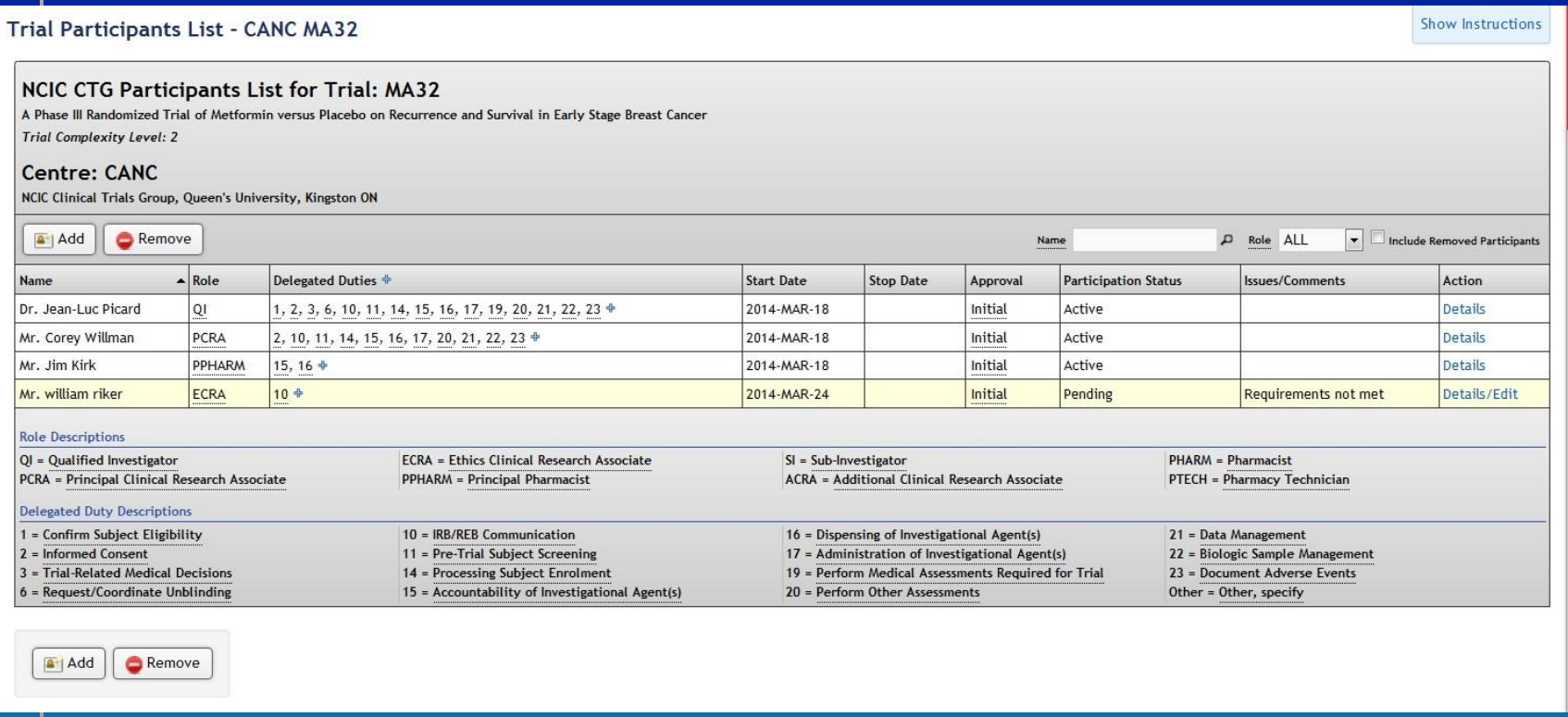
Training Name	Completed?	Date Completed
NCI US	Yes	2005-OCT-04

Conflict of Interest Disclosure

COI Form (pdf)

Date of last completed COI form: **2011-JUN-24**

RIPPLE – Participants List



Trial Participants List - CANC MA32

Show Instructions

NCIC CTG Participants List for Trial: MA32

A Phase III Randomized Trial of Metformin versus Placebo on Recurrence and Survival in Early Stage Breast Cancer

Trial Complexity Level: 2

Centre: CANC

NCIC Clinical Trials Group, Queen's University, Kingston ON

Add | Remove | Name | Role: ALL | Include Removed Participants

Name	Role	Delegated Duties	Start Date	Stop Date	Approval	Participation Status	Issues/Comments	Action
Dr. Jean-Luc Picard	QI	1, 2, 3, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23	2014-MAR-18		Initial	Active		Details
Mr. Corey Willman	PCRA	2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23	2014-MAR-18		Initial	Active		Details
Mr. Jim Kirk	PPHARM	15, 16	2014-MAR-18		Initial	Active		Details
Mr. william riker	ECRA	10	2014-MAR-24		Initial	Pending	Requirements not met	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; 10 = IRB/REB Communication; 16 = Dispensing of Investigational Agent(s); 21 = Data Management
2 = Informed Consent; 11 = Pre-Trial Subject Screening; 17 = Administration of Investigational Agent(s); 22 = Biologic Sample Management
3 = Trial-Related Medical Decisions; 14 = Processing Subject Enrolment; 19 = Perform Medical Assessments Required for Trial; 23 = Document Adverse Events
6 = Request/Coordinate Unblinding; 15 = Accountability of Investigational Agent(s); 20 = Perform Other Assessments; Other = Other, specify

Add | Remove

Pending

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

Req. roles pending since: 2014-MAR-18

Required Roles

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

Reports

Participants List Report
Trial Signature Report

Summary

All of the required roles have been added to the participants list, but not all are active. The pending records are either awaiting their assigned start dates, have not yet met all their requirements, or have not yet been approved by the currently listed Qualified Investigator.

Hide Required Roles

- Add, remove, change participants, roles & duties
- Can be done by RRA or PLA
- **QI must approve all changes electronically** (additions/removals/edits in personnel/roles/duties)

NCIC CTG
NCIC GEC

Who Will Be Using It?

- All members - view/make changes to their own account information
- Remote Roster Administrators (RRA)
- Participant List Administrators (PLA)
- Qualified Investigators (QI) for approvals

RRA

RRA = Remote Roster Administrator

Who Are They?

- 2-3 per site to ensure coverage
- Must submit an RRA Designation Form (by 2014APR11) signed by RRA and Centre Rep to add/replace RRAs
- Must have an active CTG membership account and prior to first action in RIPPLE complete the confidentiality attestation in RIPPLE

RRAs – What Can You Do?

- Must approve new membership account requests for their centre
- Can add/remove membership accounts
- Can view/edit contact information for all member at their site
- Upload credentialing documentation for members
- Create/edit trial PLs (all changes must be approved by QI)
- Receive notifications for membership/PL issues at their site

PLA

PLA = Participants List Administrator

Who Are They?

- Option to designate PLAs at your centre (unlimited number)
- Helpful at larger centres where trial PCRA may submit all PL/PLCFs
- Assignment of PLAs done within RIPPLE by RRA and can be updated within RIPPLE as needed
- Must have an active CTG membership account and prior to first action in RIPPLE complete the confidentiality attestation in RIPPLE

PLAs – What Can You Do?

- Can be designated for specific trials or all trials at that centre
- Can create/edit PLs for these trials
- All changes to PLs must still be approved by QI

Participant Signatures

- Signature sheet is an essential document according to GCP
- Participant Signature Form (PSF) to be submitted for all site research personnel
- Only required for individuals active on a PL
- Monthly reminders to participant
- “One time” only form – will be used to generate Trial Signature Reports for all trials
- Will start with active MA.32 trial participants
- Plan in place to assist with initial upload

Built-In Notifications/Reminders

- Automatic reminders set up for various time points/functions, for example:
  - When a participant is added to the PL but does not meet credentialing requirements
  - When a participants becomes “active” on a trial PL (ie. requested start date arrived, credentialing requirements met and QI approved)
  - Missing mandatory role for a trial
  - QI approvals required
- Minimum frequency/personnel programmed but some changes permitted by centre (e.g. additional people to receive notifications)
- Try to batch notifications/reminders as much as possible

Are Reports Available?

- Various Reports will be available to be run for both sites and central office
- For example:
  - Trial Signature Report
  - Trial Participants List Report

When Is This All Being Implemented?

- Member registration component for ALL Canadian centres and MA.32 PL will be rolled out 2014APR28 (current Canadian Membership roster will be available)
- PL component for other trials to follow shortly thereafter (study specific memos sent)
- RIPPLE Participants List will reflect new policy and guidance
  - "paper" PL/PLCF will too, new versions will be available on applicable Trial websites April 28th

Why Is MA.32 First ?

- No longer accruing patients in case of any technical issues with the system
- Large number of Canadian centres involved
- No additional trial specific training/credentialing requirements
- IMPORTANT: 3 week “grace” period for paper PL/PLCFs for trials rolling into RIPPLE (but prefer use RIPPLE!)
  - After that date forms will be returned and centre notified to make changes directly in RIPPLE

What about out of date information?

- What to do if you have members that are no longer at your centre appearing in RIPPLE?
  - Enter leave date in roster (this will automatically add stop date for PLs in RIPPLE for QI approval) and RRA approves, submit paper PLCFs for studies not in RIPPLE
- What to do if you have participants that are no longer on a trial?
  - Add stop date in RIPPLE for QI approval
  - Submit PLCF for trials not in RIPPLE

Where to go for help?

- Useful resources will be available in the RIPPLE system including
  - Training slide decks
  - Training videos
  - Copies of Memos and external bulletins
  - Frequently asked questions
  - Forms
  - ripple@ctg.queensu.ca