1 Introduction

When acting as the sponsor of NCTN trials in Canada (CCTG-Led or Intergroup), CCTG as holder of the NCTN grant, as well as its member sites included in the grant, are required to comply with the grant terms and the NCTN program guidelines. This includes following the requirements for identity proofing (through ID.me) and two factor authentication. The requirements apply to any person with a CTEP-IAM account and any system using CTEP-IAM credentials.

This reference document highlights the operational needs and considerations for CCTG Canadian site NCTN trial participants to hold CTEP-IAM accounts.

1.1 Acronyms

ACRA	Additional Clinical Research Associate
CTSU	Clinical Trials Support Unit
ECRA	Ethics Clinical Research Associate
IB	Investigator Brochure
QI	Qualified Investigator
PCRA	Principal Clinical Research Associate
PL	Participants List
PLA	Participant List Administrator (for the CCTG RIPPLE system)
PHARM	Pharmacist
PMB	Pharmaceutical Management Branch
PPHARM	Principal Pharmacist
RIPPLE	Roster Interface Program and Participants List Environment (CCTG system)
RRA	Remote Roster Administrator (for the CCTG RIPPLE system)
SI	Sub-Investigator

2 CTEP Systems and Operational Need for Access by Trial Role

The table below lists CTEP systems relevant to NCTN trial conduct, explains their functionality and describes the operational need for system access (i.e. holding a CTEP-IAM account) by trial site participant role.

CTEP System	**System Functionality**	**Trial Site Participants with Operational Need for System Access**
RCR	Registration and Credentialing Repository	QIs, SIs and any other role who requires CTEP systems access (see also below)
OPEN	Patient Enrollment, Funding OPEN includes the following person types: Treating Investigator, Consenting Person, Primary CRA for Participant, Contact Person Sample Submission and Site Registrar)	Investigator and CRA roles

CTEP System	System Functionality	Trial Site Participants with Operational Need for System Access
CTEP-AERS	SAE Reporting	Investigator and CRA roles
PMB-AURORA	Drug Management Ordering, IB access, Drug Accountability	Pharmacists
Rave EDC (incl modules, e.g. ePRO/Patient Cloud module)	Data Entry / Data Management	Investigator and CRA roles
SDP	Supporting Document Portal Upload / Access Supporting Documents	Investigator and CRA roles
CLASS	Training	Predominantly Investigator and CRA roles; may apply to Pharmacists (e.g. PMB related process training)
DTL	Delegated Task Log Used for trials with a US IND.	All listed on the RIPPLE PL, who either have a RIPPLE role, or have been delegated a RIPPLE duty, that map to a DTL mandatory task (see section 4).
CTSU Webpage	• Trial Information Webpage (incudes access to SDP and SQP) • Regulatory Submission Portal • Provider Association	Investigator and CRA roles *Note: The Regulatory Submission Portal and Provider Association only apply to trials with protocol specific requirements for credentialing (e.g. radiotherapy or radiopharmaceutical credentialing)*
DQP	Data Quality Portal Form and Query Reminders	Investigator and CRA Roles
TRIAD / IROC	RTQA documentation submission Medical images and related electronic data	Investigator and CRA Roles

3 CCTG Participants List and CTEP Accounts

For all CCTG trials, the Trial QI, as well as clinical trial personnel performing significant trial-related duties delegated by the QI, should be listed on the CCTG Trial PL in RIPPLE. The Trial PL will mandate applicable training and credentialing requirements depending on the trial, including (for NCTN trials) an active CTEP-IAM user account with appropriate registration type for applicable roles.

For NCTN trials under a US IND, NCTN guidelines state that to evaluate the roles and responsibilities of any individual contributing efforts to a clinical trial, a Delegation of Tasks Log (DTL) must be maintained. The DTL is to list anyone who contributes significant trial-related duties. Therefore, in additional to CCTG Trial PL, Canadian sites participating on NCTN trials through CCTG will also maintain a DTL and DTL task assignments. The DTL is managed directly in RIPPLE, which is integrated with the NCI-DTL via real-time electronic data transfer. Anyone listed on the DTL will require an active CTEP-IAM user account with appropriate registration type.

The two tables below describe the operational need for holding CTEP-IAM accounts based on PL roles, both for NCTN trials without (section 3.1) and with (section 3.2) a DTL.

3.1 NCTN Trials without a DTL - Trial Roles on the CCTG Trial Participants List and Operational Need for CTEP-IAM Accounts

CTEP-IAM Account Requirement Category	CCTG PL Roles	Comments
Need CTEP Account	QI, all SIs, PCRA and PPHARM (trials with PMB agents only)	Collectively these roles must have access to all CTEP systems (see section 2) necessary for study conduct
Recommend have CTEP Account	At least one more ACRA and PHARM (coverage purposes)	
No operational need for an CTEP account	All other roles *e.g. CRAs who only conduct patient clinic visits; ECRAs (all ethics / regulatory documents routed via CCTG); etc.*	Persons on the PL who do not have CTEP-IAM accounts would also not be able to perform those delegated duties from the RIPPLE list, for which an account is required. For example, duty #21 (Data Management) in RIPPLE should generally not be assigned to those with no CTEP-IAM accounts since not able to access Rave for data entry / management.

3.2 NCTN Trials with a DTL - Trial Roles on the CCTG Trial Participants List and Operational Need for CTEP-IAM Accounts

CTEP-IAM Account Requirement Category	PL Roles	Comments
Need CTEP Account	QI, all SIs, PCRA and PPHARM **AND** any other roles with RIPPLE duties (#1, 2, 14, 15, 19 or 21) mapping to a required DTL task **AND** any site members acting as a RIPPLE PLAs or RRAs (see also section 4)	Collectively these roles must have access to all CTEP systems (see section 2) necessary for study conduct
Recommend have CTEP Account	At least one more ACRA and PHARM (coverage purposes)	
No operational need for an CTEP account	All other roles *e.g. CRAs who only conduct*	These persons cannot be assigned RIPPLE duties 1, 2, 14, 15, 19 or 21 (see also section 4) or act as

CTEP-IAM Account Requirement Category	PL Roles	Comments
	patient clinic visits; ECRAs (all ethics / regulatory documents routed via CCTG and RIPPLE duty #10 does not map to a required DTL task – see slide 3)	RIPPLE PLAs or RRAs.

4 DTL Required Tasks and RIPPLE Mapping

The trial PL in the CCTG RIPPLE system identifies trial participants by role (e.g. QI, SI, PCRA). Further, each role in addition to the QI, may have delegated duties designated within RIPPLE. The full list of RIPPLE roles and delegated duties (numbered 1 to 23) is provided in the Appendix at the end of this document.

In the DTL, trial participants are identified based on tasks, with 12 different tasks being 'required'.

The table below lists the roles / duties on the RIPPLE PL which map to required tasks on the DTL. Because the DTL is a CTEP system, a participant on a RIPPLE PL who has a role or delegated duty mapping to a DTL required task must, by extension, also hold an active CTEP-IAM user account. For example, an ACRA with delegated duty #2 (informed consent) must have a CTEP-IAM account because they will also be listed on the DTL with the required task 'Consent Person'.

Required DTL Task Name	Mapped RIPPLED Role or Duty
Clinical Investigator	QI role
DTL Administrator	PLA and RRA roles
Consenting Person	Informed Consent (RIPPLE duty #2)
Eligibility Assessments	Confirm subject Eligibility (RIPPLE duty #1)
End Point Assessments	Perform Medical Assessments Required for Trial (RIPPLE duty #19)
Enrolling person / Treating Investigator	QI and SI roles
History and Physical Assessment	Perform Medical Assessments Required for Trial (RIPPLE duty #19)
IND Prescribing	QI and SI roles
IP Accountability	Accountability of Investigational Agent(s) (RIPPLE duty #15)
OPEN Registrar	Processing Subject Enrolment (RIPPLE duty #14)

Required DTL Task Name	Mapped RIPPLED Role or Duty
Rave CRA	Data Management (RIPPLE duty #21)
Toxicity Assessment	Perform medical assessments (RIPPLE duty #19)

5 Appendix

RIPPLE 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

RIPPLE Delegated Duty Descriptions

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

6 References

1. Participants List & Qualified Investigator Delegation of Duties (CTG-REF-0023): https://www.ctg.queensu.ca/docs/trials/generic_forms/PL_PLCF/ctg-ref-0023_PL_and_QI_Delegation_of_Duties.pdf

2. NCTN Program Guidelines: https://ctep.cancer.gov/initiativesPrograms/nctn.htm

3. CTEP Identity and Access Management (IAM) Website: https://ctep.cancer.gov/branches/pmb/associate_registration.htm

4. Guidelines for Auditing Clinical Trials for the NCI NCTN Program: https://ctep.cancer.gov/branches/ctmb/clinicalTrials/docs/NCTN_Auditing_Guidelines.pdf