NCIC Clinical Trials Group Policy for Investigator Credentialing CTG-POL-0011 v0007 (2013Apr07)

NCIC CTG Policy for Investigator Credentialing

- This policy establishes guidelines and procedures for determining investigator credentials and requirements for participation as an investigator on NCIC Clinical Trials Group (CTG) clinical trials.

Investigator Registration

- Investigators interested in becoming members register with NCIC CTG as an investigator and annually renew their registration.
- Registration requires submission of a current CV and Investigator Registration Form

Investigator Type

- Investigator category determining qualifications for trial participation as:
  - Qualified Investigator (QI)
  - Sub-Investigator (SI)
- Trial-related duties may be limited depending on Trial Complexity Level and Investigator Type

Investigator Type

Type 1: Medical doctor with institutional privileges to independently provide care to cancer patients (e.g. Medical Oncologist)

Type 2: Medical doctors providing care to cancer patients in a limited/supervised setting (e.g. Fellow, GPO)

Type 3: Health care professional providing care to cancer patients in a limited/supervised setting (e.g. ACNP, Physician Assistant)

Trial Complexity Level

- **Level 1:** High Risk and Complexity
  - Requires sub-specialization in oncology including experience evaluating highly complex interventions
- **Level 2:** Standard Risk and Complexity
  - Testing oncologic-directed medical interventions (e.g. a drug, radiation therapy, surgical technique)
- **Level 3:** Low Risk and Complexity
  - Testing common standards of care and/or interventions that do not require specialized oncology certification

NCIC CTG Investigator Roles by Trial Risk & Complexity

Trial Risk Level	Investigator Type		
	TYPE 1	TYPE 2	TYPE 3
LEVEL 1	QI/SI	SI*	SI*
LEVEL 2	QI/SI	QI/SI	SI*
LEVEL 3	QI/SI	QI/SI	QI/SI

* Delegation of duties 'Confirm Eligibility' and 'Trial-Related Medical Decisions ' are not permitted. Not permitted to be the enrolling investigator on NCIC CTG trials

Participants List & Qualified Investigator Delegation of Duties CTG-REF-0023 v0003 (2014Feb17)

Participants List

- List of qualified CTP at centre for a trial; required prior to centre local activation and for all additions and removals of CTP
- PL requirements include:
  - Full name of CTP
  - Designated trial role (may have ≥1 role)
  - New role PTECH (optional)
  - Delegated duties (each CTP must have ≥1 duty)
  - Start (and stop) dates for participation
  - QI approval of all CTPs
  - Essential/mandatory roles QI, PCRA, ECRA, PPHARM (trials with investigational agents)

Delegated Duties

- QI should maintain a list of appropriately qualified person to whom they have delegated significant trial-related duties
  - QI & SI (Type 1): All duties permitted
  - SI (Type 2 & 3): Duties are dependent on Trial Complexity Level
  - CRAs: Specified duties based on CRA role
  - PHARM/PTECH: Study Drug Management

Permissible Delegations by Role

#	Term	QI	SI	PCRA ACRA	ECRA	PPHARM PHARM PTECH
1	Confirm Subject Eligibility	☑	☑[1]			
2	Informed Consent	☑	☑	☑		
3	Trial-Related Medical Decisions	☑	☑[1]			
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 Trial Medical Assessments	☑	☑			
20	Perform Other Assessments	☑	☑	☑		
21	Data Management	☑	☑	☑		
22	Biologic Sample Management	☑	☑	☑		
23	Document Adverse Events	☑	☑	☑		

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[1]Level 1 Trial must be Type 1 Investigator; Level 2 Trials must be Type 1 or Type 2 Investigator

Mapping Investigator Roles

Previous Term	New Term
Principal Investigator (PI) ➡	**Qualified Investigator (QI)**
Additional Investigator (AI) ➡	**Sub Investigator (SI)**
Clinical Investigator (CI) ➡	**Sub Investigator (SI)**

Mapping Delegated Duties

Retired Duties	
#	Term
4	Evaluation of Trial Lab Results [Incorporated into Duty 19]
5	Assess Adverse Events [Incorporated into Duty 19]
9	Perform Physical Exams [Incorporated into Duty 19/20]
12	CRF Completion/Corrections [Incorporated into Duty 21]
13	Query Resolution [Incorporated into Duty 21]
18	Other: Specify [Incorporated into Duty Other]