

Canadian Cancer Trials Group Policy for Investigator Credentialing

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Approval			
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Revision History		
Version	Date	Revision Log
V010	January 22, 2020	<ul style="list-style-type: none"> update ICH to International Council for Harmonisation
V009	November 20, 2014	<ul style="list-style-type: none"> Updated to include the Initiative to Streamline Clinical Trials and Qualified Investigator assignment of delegation.
V008	May 1, 2014	<ul style="list-style-type: none"> Policy section 7.2 was updated for consistency throughout the policy regarding requirements for investigator credentialing and to clarify the definition of Medical Fellow.
V007	April 2, 2013	<ul style="list-style-type: none"> Revised policy format to new CCTG policy template. Included new term <i>CCTG Investigator Registration</i> and revised CV submission from every 2 years to annual submission. Revised <i>Investigator Credentialing Term</i> to <i>Investigator Type 1/2/3</i>. Revised <i>Trial Complexity Level</i> to identify NDA trials as <i>Level 1</i>. Moved <i>Delegation of Duties</i> to a separate guidance document.
V006	June 15, 2012	<ul style="list-style-type: none"> Policy sections 8, 9, 10 and 11 were revised to 7, 8, 9, and 10.
V005	April 25, 2012	<ul style="list-style-type: none"> CTG-POL-0011 V5 CCTG Policy for Investigator Credentialing and Delegation of Duties replaces AMG-REF-0012 Guidance for Investigators: Delegation of Study Related Duties. Update of terms in compliance with Health Canada Regulations. Addition of guidance for QIs for trial complexity and delegation.
V004	April 6, 2010	<ul style="list-style-type: none"> Initial release of AMG-REF-0012 in the CCTG electronic document management system (V001-V003 pre-dated this system).

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1 Purpose

This policy establishes guidelines and procedures for determining investigator credentials and requirements for participation as an investigator on Canadian Cancer Trials Group (CCTG) clinical trials.

2 Scope

This policy applies to all investigators participating on CCTG clinical trials where CCTG is responsible for oversight of the centre. This includes Canadian member centres that have a Participating Centre Agreement (PCA) and also applies to all investigators participating on CCTG clinical trials at non-Canadian centres that have a Single-Study Investigator Agreement.

3 Definitions

3.1 Terms

Centre: The location(s) where clinical trial-related activities are conducted.

Investigator Type: A category for the investigator's credentials that determines their qualifications for participation on CCTG clinical trials. It is assigned by CCTG upon CCTG Investigator Registration.

CCTG Membership Roster: A database system that stores address/contact information, credentialing requirements and trial participation details for participants on CCTG clinical trials.

CCTG Investigator Registration: The process where participants initially register with CCTG as an investigator and annually renew their registration. This includes the submission of the CCTG Investigator Registration Form and a current curriculum vitae (CV).

Participating Centre Agreement: A contractual agreement completed between CCTG and a centre (known as a CCTG member centre, clinical trial site etc.) that permits the centre to participate on all CCTG clinical trials (as appropriate). The agreement is signed by a representative of the centre and the CCTG Group Director. All investigators participating in CCTG trials within the centre are bound by the terms listed in the PCA.

Qualified Investigator (QI): *The person responsible to the sponsor for the conduct of the clinical trial at a clinical trial site, who is entitled to provide health care under the laws of the province where that clinical trial site is located, and who is (a) in the case of a clinical trial respecting a drug to be used for dental purposes only, a physician or dentist and a member in good standing of a professional medical or dental association; and (b) in any other case, a physician and a member in good standing of a professional medical association. (chercheur qualifié) C.05.010. (e) at each clinical trial site, there is no more than one qualified investigator.* [Health Canada Regulations: Division 5 – Drugs for Clinical Trials Involving Human Subjects](#)

The role QI is the lead role for a trial at a centre and includes responsibility to the sponsor and Research Ethics Board as detailed in the PCA. CCTG requires the QI to be sufficiently experienced within the field of oncology and have hospital privileges that permit independent practice. There may however, be additional trial specific criteria in place dependent on the risk and complexity of the trial. The QI is required to document the delegation of significant trial related duties on the trial. Based on the recommendations of the Initiative to Streamline Clinical Trials (ISCT), QIs, while ultimately responsible for delegation, may assign an appropriately qualified delegate to coordinate the delegation of duties to appropriately qualified individuals, and

create and maintain the delegation list. (Note: Amendments/clarifications to existing Institution standard operation procedures are recommended if not consistent with the ISCT recommendations.)

Single-Study Investigator Agreement: A contractual agreement completed between CCTG and a centre that permits the centre to participate on a specific CCTG clinical trial. The agreement contains the same pledges as the PCA, but the terms apply to a single study and the particular investigators named.

Specialty Practice: The field or practice of medicine in which the physician or health care professional specializes.

Sub Investigator (SI): *Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).* [International Council for Harmonisation \(ICH\) Good Clinical Practice \(GCP\): Guidelines for Good Clinical Practice](#)

The CCTG role of SI is further defined in section 7.2.

Trial Complexity Level: A category for the risk and complexity associated with a clinical trial as assigned by CCTG.

3.2 Acronyms

CTA	Clinical Trials Application
CTEP	Clinical Trials Evaluation Program
CCTG	Canadian Cancer Trials Group
CV	Curriculum Vitae
GCP	Good Clinical Practice
ICH	International Council for Harmonisation
ISCT	Initiative to Streamline Clinical Trials
PCA	Participating Centre Agreement
QI	Qualified Investigator
SI	Sub Investigator

4 Regulations

This policy is governed by the following guidelines and regulations:

- [Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects](#)
- [ICH GCP: Guidelines for Good Clinical Practice](#)
- [Health Canada Regulations: Division 5 – Drugs for Clinical Trials Involving Human Subjects](#)
- U.S. clinical trial regulations/policies (as applicable) including:
 - [Food and Drug Administration Code of Federal Regulation Title 21 Part 312: Investigational New Drug Application](#)
 - [Clinical Trials Evaluation Program \(CTEP\) Investigator Registration](#)
- [Initiative to Streamline Clinical Trials \(ISCT\)](#)

5 Background

As sponsor, CCTG will ensure trials are conducted at centres by qualified personnel. Standard professional credentialing processes are in place to ensure licensed personnel are appropriately qualified with respect to the provision of care within their professional scope of practice. These include national and provincial credentialing systems as well as local institutional credentialing procedures. Applicable requirements for professional accountabilities, supervision and/or delegation are defined via these mechanisms and should be taken into consideration in the local clinical research setting.

Within the research domain of clinical trials, CCTG will ensure clinical trial personnel are appropriately qualified through the CCTG Membership Roster in compliance with applicable regulations and guidelines.

6 Policy

It is CCTG policy to credential investigators prior to participation on its clinical trials. Investigators must meet the applicable credentialing requirements defined by CCTG according to requirements of the trial being conducted.

7 Procedures

CCTG will use the following procedures to credential investigators and ensure investigators are qualified to participate on CCTG clinical trials.

7.1 Investigator Credentialing Requirements

Investigators interested in becoming members register with CCTG as an investigator and annually renew their registration. This includes the submission of the CCTG Investigator Registration Form and a current curriculum vitae (CV).

There are additional credentialing requirements for participation as an investigator on CCTG clinical trials that are not included in the investigator registration. These include:

- Completion of GCP training program
- Completion of training in the Protection of Human Research Participants
- Annual completion of CTEP Investigator Registration; required for all investigators participating on trials sponsored by CTEP
- Completion of Health Canada Qualified Investigator Undertaking Form; only required for QIs participating on trials under a Clinical Trials Application (CTA) in Canada

7.2 Investigator Types

Investigators will be credentialed by CCTG based on their most recent CCTG Investigator Registration Form and current curriculum vitae (CV) and will be assigned an *Investigator Type* accordingly.

The selection and roles of SIs are the responsibility of the QI. Permissible delegation of significant trial-related duties are to follow local policy, however the following restrictions may apply depending on the *Trial Complexity Level* and *Investigator Type* (see *Appendix 1*):

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

The assigned *Investigator Type* will be used to determine their trial participation as follows:

Type 1 Investigator: A medical doctor licensed to practice at the centre, with hospital/institutional privileges, to independently provide care to cancer patients. There are no restrictions to *Type 1 Investigator* participation. *Type 1 Investigators* include, but are not limited to, the following specialty practices: Medical Oncology, Gynecological Oncology, Radiation Oncology, Dermatology, Hematology, Thoracic Surgery, and Urology.

Type 2 Investigator: A medical doctor providing care to cancer patients in a limited or supervised setting. *Type 2 Investigators* have restricted duties on high risk trials (i.e. *Trial Complexity Level 1*) and include the following participants:

- **Medical Fellows:** A medical doctor enrolled in a post specialization training program in an oncology related discipline which includes accountability to, but not necessarily direct supervision by, a licensed investigator at their centre.
- **General Practitioner in Oncology:** A medical doctor without oncology specialty licensing in the geographic location where the trial is to be conducted (e.g. province) and with institutional privileges to provide care to cancer patients. Provision of care includes a range of activities that are accountable to, but are otherwise unsupervised by another investigator.

Type 3 Investigator: A health care professional providing care to cancer patients in a limited or supervised setting. *Type 3 Investigators* have restricted duties on both high and standard risk trials (i.e. *Trial Complexity Levels 1 and 2*) and include the following participants:

- **Acute Care Nurse Practitioner (or Advance Practice Nurse):** A registered nurse with Masters level training that is associated with separate institutional and potentially geographic (e.g. provincial) credentialing based on training to provide care within the institution through a series of delegated responsibilities. These responsibilities include roles that range from independent decision making to direct supervision.
- **Physician Assistants:** A graduate of a Master's level Physician Assistant program.
- **Other Medical Professionals:** Including, but not limited to, physiotherapists and kinesiologists.

7.3 Trial Complexity Level

The trial risk and complexity level is used to determine the requirements for the QI (see *Appendix 1*). CCTG will assign the following trial complexity levels:

Level 1: High Risk and Complexity

These are trials that require sub-specialization within the field of oncology, including experience in the conduct of clinical research evaluating highly complex interventions. These trials will be activated only at selected centres with QIs that have experience with the specific intervention included in the evaluation. The QI must be a *Type 1 Investigator*. Examples include:

- Phase I Investigational New Drug trials
- Specialized radiation therapy technology (e.g. brachytherapy)
- Specialized and/or novel surgical procedures and stem cell transplantation
- Trials for which the agent is unapproved for any indication (i.e. registration or New Drug Application track studies, although trials in an adjuvant population or where drug is approved for an alternate indication may not necessarily be considered Level 1)

Level 2: Standard Risk and Complexity

These are trials that test an oncologic-directed medical intervention (e.g., a drug, radiation therapy, surgical technique). These trials require that the QI be sufficiently experienced within the

field of oncology and have institutional privileges that permit both independent practice and a QI role. The QI may be a *Type 1* or *Type 2 Investigator*.

Level 3: Low Risk and Complexity

These are trials testing common standards of care and/or interventions that do not require specialized oncology certification. These trials will not be associated with a CTA. Some trials (e.g. those testing a life-style intervention) will require unique credentials that are unassociated with oncology certification and/or a medical degree (e.g. specialized counseling). The QI may be a *Type 1*, *Type 2* or *Type 3 Investigator*. Examples include:

- Symptom control trials testing commonly used interventions
- Trials of cancer prevention
- Trials testing life-style interventions

8 Exception to Policy

Investigators participating on CCTG clinical trials where CCTG is not responsible for oversight of the centre are exempt from this policy. In this case, another cooperative group or contract research organization has been delegated the oversight responsibility as the sponsor and investigators will be credentialed according to their policies.

9 Appendix

Appendix 1: CCTG Investigator Roles by Trial Complexity Level

Investigator Trial	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

* Permissible delegation of significant trial-related duties are to follow local policy, however the following restrictions apply:

- Delegation of duties Confirm Eligibility and Trial-Related Medical Decisions are not permitted
- Not permitted to be the enrolling investigator on CCTG trials