NCI Experimental Therapeutics Clinical Trials Network

A program of the National Cancer Institute of the National Institutes of Health

TRIAL CONDUCT
Intended for those at clinical sites **conducting** ETCTN trials

ETCTN Regulatory Processing Information Page

1. Introduction

The Regulatory application is the Cancer Trials Support Unit (CTSU) application that tracks regulatory compliance for NCI-sponsored trials, including those conducted by the National Clinical Trials Network Groups, the ETCTN organizations, and other networks.

All **new** trials opened under the ETCTN program use the CTSU's central regulatory processing system. All regulatory documentation (including protocol-specific requirements [PSRs], e.g., special investigator credentialing, radiation credentialing) must be submitted to the CTSU Regulatory Office via the Regulatory Submission Portal available under the Regulatory section of the CTSU members' website (username and password required). Do not submit regulatory documentation to the lead institution or Cancer Therapy Evaluation Program (CTEP) Protocol and Information Office (PIO). Site staff may use the CTSU website to check the status of submissions and the overall regulatory status of a trial at their site prior to enrolling patients.

Trials activated **prior to** the implementation of the ETCTN program that have not transitioned into the ETCTN mechanism will continue to follow their existing procedures for submission of regulatory documentation. Sites will be notified in advance of any change in procedures if there are trials identified for transitioning into the ETCTN in the future.

Each protocol includes information regarding the regulatory and protocol-specific documentation required for the trial, as well as which submission process to follow.

2. Submission of Regulatory Documentation

Refer to the Regulatory section of the CTSU members' website for an overview of the Regulatory application and the regulatory submission process.

2.1 Sites using the NCI CIRB

Domestic ETCTN sites must participate on trials through the NCI Central Institutional Review Board (CIRB) program. For more information on the NCI CIRB, refer to the *ETCTN NCI CIRB Initiative Information Page*. Sites participating in the NCI CIRB program do **not** need to submit IRB approvals to the CTSU Regulatory Office for trials that are reviewed by the CIRB; this is handled automatically by a web-service between CIRB's IRBManager and the CTSU Regulatory application. However, these sites do still need to:

a) Submit a Study-Specific Worksheet (SSW) about Local Context to the CIRB;

b) Ensure that their site preferences for how CIRB approvals should be applied are on file with the CTSU; and

c) Submit any additional PSRs to the CTSU Regulatory Office.

All protocol-specific documentation should be submitted using the Regulatory Submission Portal under the Regulatory section of the CTSU members' website.

2.2 Canadian Sites using Local IRBs

Canadian ETCTN sites need authorization to participate in ETCTN studies from the Lead Academic Organization (LAO) and CTEP. Once approved, Canadian sites must submit their Research Ethics Board Attestation (REBA), Qualified Investigator Undertaking (QIU), and Clinical Trials Site Information (CTSI) Form to the Clinical Trials Application (CTA) holder in Canada (generally LAO-11030), if applicable. The CTA holder will inform the CTSU when all regulatory documentation is complete.

Canadian sites are not members of the NCI CIRB and must therefore continue to use their local IRB as the IRB of record. Submit local IRB approvals for Canadian sites, as well as any other PSRs, to the CTSU Regulatory Office using the Regulatory Submission Portal under the Regulatory section of the CTSU members' website.

3. Checking Regulatory Status

Organization and site staff can check the status of their regulatory approvals for studies maintained in the Regulatory application within the Regulatory section of the CTSU members' website by clicking on Site Registration (for regulatory status information) or the Regulatory Submission Portal (for information on the status of previously submitted documents).

Staff can also check the list of PSRs for any given trial by clicking on the Protocol Requirements section and entering the trial of interest.

4. For Questions and Support

For questions about regulatory processing, contact the Regulatory Help Desk:

- CTSU Regulatory Help Desk: 1-866-651-CTSU (2878) or CTSURegHelp@coccg.org

For questions about the CIRB-CTSU process, or to set CIRB site preferences, contact the Regulatory Help Desk:

- CTSU Regulatory Help Desk: 1-866-651-CTSU (2878) or CTSURegPref@ctsu.coccg.org

For all other CTSU-related questions, contact the CTSU Help Desk:

- CTSU Help Desk: 1-888-823-5923 or ctsucontact@westat.com

CTSU Help Desk hours are 9:00 am – 6:00 pm ET Monday-Friday (excluding holidays).

For questions related to the CIRB program, contact the CIRB Helpdesk:

- CIRB Help Desk: support@ncicirbcontact.zendesk.com