
ETCTN Regulatory Processing Information Page

1. Introduction

The Regulatory Support System (RSS) is the Cancer Trials Support Unit (CTSU) database that tracks regulatory compliance and roster data 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 will use the CTSU's central regulatory processing system. All regulatory materials and protocol-specific materials (e.g., special investigator credentialing, radiation credentialing) will 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). Regulatory materials will not be submitted 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 ETCTN mechanism will continue to follow their existing procedures for submission of regulatory materials. 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 will include information regarding the regulatory and protocol-specific materials required for the trial, as well as which submission process to follow.

2. Submission of Regulatory Materials

Refer to the [Regulatory section](#) of the CTSU members' website for an overview of RSS 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 will **not** need to submit IRB approvals to the CTSU Regulatory Office for trials that are reviewed by the CIRB; this will be handled automatically by a web-service between CIRB's IRB Manager and RSS. However, these sites will 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 protocol-specific requirements to the CTSU Regulatory Office. All protocol-specific materials 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 will 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. Local IRB approvals for Canadian sites, as well as any other protocol-specific requirements, should be submitted 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 RSS 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 protocol-specific requirements 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 CTSU Help Desk:

- CTSU Regulatory Help Desk: 1-866-651-CTSUS (2878) or CTSUSRegHelp@coocg.org
- CTSU Help Desk: 1-888-823-5923 or ctsuscontact@westat.com

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

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

CIRB Help Desk: NCICIRBContact@emmes.com