



Experimental Therapeutics Clinical Trials Network
Team Driven. Cancer Therapy Focused.

National Cancer Institute at the National Institutes of Health

TRIAL CONDUCT

Intended for those at clinical sites
conducting ETCTN trials

ETCTN Regulatory Processing Information Sheet

1. Introduction

The Regulatory Support System (RSS) is the database housed at the Cancer Trials Support Unit's (CTSUS) Central Regulatory Office that tracks regulatory compliance for NCI-sponsored trials, including those conducted by the NCTN Groups, the ETCTN organizations, and other networks.

All new trials opened under the ETCTN program will utilize 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 Central Regulatory Office and not to the lead institution or Cancer Therapy Evaluation Program (CTEP) Protocol and Information Office (PIO). Site staff will be able to use the CTSU website to check the regulatory status of these trials at their site prior to attempting to enroll patients.

Please note that the process for submitting regulatory materials to the CTSU Regulatory Office is different depending on whether a site is using the NCI Central Institutional Review Board (CIRB) or using their local IRB. This is outlined in Sections 2.1. and 2.2, respectively.

Trials activated prior to the implementation of the ETCTN program will continue to follow their existing procedures for submission of regulatory materials. However, some trials will transition into central regulatory processing via the CTSU Central Regulatory Office; in those cases, sites will be given adequate advance notice of any change in procedures.

Each trial's protocol document will include information on what regulatory and protocol-specific materials are required for that trial, as well as which submission process to follow.

2. Submission of Regulatory Materials

Please see the Regulatory tab on the CTSU members' website (username and password required) for an overview of RSS and the regulatory submission process.

- CTSU website Regulatory tab (username and password required):
<https://www.ctsus.org/RSS/default.aspx?nodeID=5>

Please also see content in the CIRB-CTSUS Integration folder under the Education & Resources tab of the CTSU members' website for more information on the interactions between the CIRB and RSS.

- CIRB-CTSUS Integration information (username and password required)
https://www.ctsus.org/pet_default.aspx?nodeID=9&module=cirb

2.1 Sites using the NCI CIRB

Sites participating in the NCI CIRB program will not need to submit IRB approvals to the Central Regulatory Office for trials that are reviewed by the CIRB; this will be handled automatically. 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 Central Regulatory Office. Any protocol-specific materials should be submitted using a cover sheet. The CTSU has one available under the Regulatory tab of the members' website (username and password required):

- [IRB/Regulatory Approval Transmittal Sheet](#) (or equivalent)

Reminder: CIRB sites will not be able to enroll patients to a CIRB-reviewed trial until the CIRB has approved the trial, the trial is activated, their SSW has been approved, and any additional protocol-specific requirements have been completed and recorded by the Central Regulatory Office.

For more information on the NCI CIRB, please see the "ETCTN NCI CIRB Initiative Information Sheet."

2.2 Sites Using a Local IRB

Sites using their own local IRB to review either CIRB-reviewed trials or non-CIRB-reviewed trials must submit certification that their IRB approves a particular trial for conduct at the site. It is important to note that this certification must be submitted a) upon original IRB approval, b) annually upon continuing review approval, and c) upon any amendment approvals that are required to be submitted to the Central Regulatory Office. *This is a change from previous N01 and U01 procedures where only the initial IRB approval needed to be submitted.*

The forms necessary for submission of IRB approvals and other required materials are posted under the Regulatory tab on the CTSU members' website (username and password required):

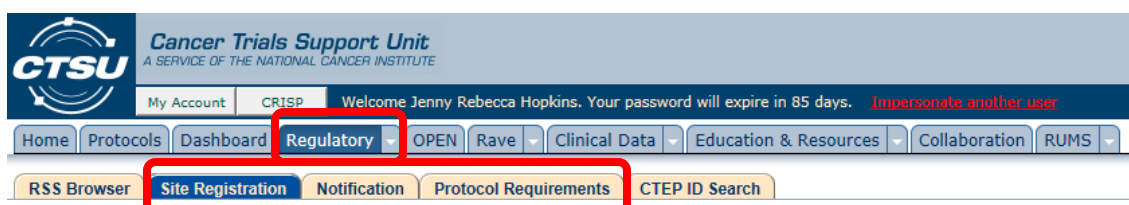
- [CTSU IRB Certification Form](#) (or acceptable substitute, e.g., IRB letter)
- [IRB/Regulatory Approval Transmittal Sheet](#)

Reminder: Non-CIRB-participating sites will not be able to enroll patients to a given trial until the trial is activated and their local IRB approval and any additional protocol-specific requirements have been submitted to and recorded by the Central Regulatory Office.

3. Checking Regulatory Status

Organization and site staff can check the status of their regulatory approvals for studies maintained in RSS via the Regulatory tab of the CTSU members' website by clicking on the Site Registration sub tab (for regulatory status information) or the Notification sub tab (for information on impending IRB approval expirations).

Staff can also check the protocol-specific requirements for any given trial by clicking on the Protocol Requirements sub tab and entering their trial of interest.





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4. For Questions and Support

Please call the CTSU Help Desk with any questions about regulatory processing.

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

Please contact the CIRB Help Desk with any questions related to the CIRB program.

- CIRB Help Desk: NCICIRBContact@emmes.com