

Welcome Packet for RTOG's International Members

Who is the Cancer Trial Support Unit (CTSU)?

The CTSU is a service of the National Cancer Institute's (NCI) Cancer Evaluation Therapy Program (CTEP). The CTSU facilitates access to clinical trials, as well as providing services on behalf of the Cooperative Groups for the benefit of the participating sites. One of the services provided by the CTSU is the centralized collection of regulatory documents by the CTSU Regulatory Office.

What is the CTSU Regulatory Office?

The CTSU Regulatory Office was officially established in January of 2003. The CTSU Regulatory Office is a service agent of the Cooperative Groups and serves as the centralized location for the collection of regulatory documents for <u>ALL</u> treatment trials (Phase I, II, & III) for NCI sponsored Cooperative Group clinical trials. The regulatory information received by the CTSU Regulatory Office is entered into the CTSU's Regulatory Support System (RSS). Once this information is entered into the RSS, it is automatically transferred to each Cooperative Group's database, so sites do not have to forward these documents to a second location.

Where is the CTSU Regulatory Office located?

CTSU Regulatory Office Coalition of Cancer Cooperative Groups 1818 Market Street, Suite 1100 Philadelphia, PA 19103

How can I submit my regulatory documents to the CTSU Regulatory Office?

Institutions can submit their regulatory documents to the CTSU Regulatory Office by Email, Fax or Mail.

CTSU Regulatory Office Email: CTSURegulatory@ctsu.coccg.org

CTSU Regulatory Office Fax Number: 215-569-0206

CTSU Regulatory Office Mailing Address: CTSU Regulatory Office

Coalition of Cancer Cooperative Groups

1818 Market Street, Suite 1100

Philadelphia, PA 19103

How long will it take the CTSU to process my regulatory documents?

Please allow 3 business days for your regulatory documents to be processed by the CTSU before checking your site registration status in the RSS via the CTSU Website.



Can I request expedited processing of my regulatory submission if I have a patient waiting?

Yes. On the first page of your regulatory submission, please write 'Urgent - Patient Waiting' and the CTSU will expedite the processing of your regulatory submission for sites that have a patient waiting for an enrollment in less than 24 hours. In addition, please call the Regulatory Help Desk if the patient must be registered within two hours. If you have previously submitted your regulatory material, please contact the CTSU Regulatory Help Desk via phone (1-866-651-CTSU (2878)) to request expedited processing.

If I have any questions, how do I contact the CTSU?

If you have any questions please call or email the CTSU:

CTSU Regulatory Office Help Desk Line: 1-866-651-CTSU(2878)

CTSU Email Address (for questions) CTSUContact@westat.com

Where can I find additional information about the CTSU Regulatory Office?

Additional information regarding the CTSU is available on the CTSU Website at https://www.ctsu.org.

There are two components of the CTSU Website, public area and member's area. To access the member's area, you must register with CTEP-IAM. Please see the attached "CTEP-IAM Fact Sheet" for registration information.

When will RTOG's International sites be required to send their regulatory documents to the CTSU Regulatory Office?

The Go Live Date for this new process is <u>January 30, 2012</u>.

Will my site be required to resubmit all of our regulatory documents previously sent to RTOG to the CTSU Regulatory Office?

No. RTOG has provide the CTSU Regulatory Office with a list of all of the regulatory document previously sent to RTOG.

For additional information, please review the attached Frequently Asked Questions (FAQs).



Frequently Asked Questions (FAQs)

How do I determine which requirements have been set up for collection by the Lead Group in the RSS for a study?

You can check the requirements currently being collected by the CTSU for a study by:

- Logging in to the CTSU Members' website
- Select the Regulatory tab
- Select the Protocol Req (requirements) tab
- Enter the protocol code in the Protocol field (or use the Pick button to select the Protocol you are interested in)
- Click Go.

All of the protocol specific requirements for that study will be displayed on the screen.

Will the CTSU accept documentation submitted in a language other than English?

The CTSU requires all regulatory documents to be submitted in English. If the documentation is submitted in another language, the CTSU will forward the packet to the Lead Group for review. It is Lead Group's decision if they will accept the documents or require an English version to be submitted.

Per RTOG's policy all regulatory documents, including the IRB/REC approved consent, are to be provided in both English and the native language. Certification of the translation is optimal but due to the prohibitive costs RTOG will accept at a minimum a verified translation. A verified translation consists of the actual IRB/REC approval letter and approved consent document in both English and the native language along with a letter on letterhead with the credentials and signature of the translator as well as signed documentation of review and verification of the translation by a third neutral party also noting their title and credentials.

Do European Union (EU) Investigators still need to email their Clinical Trials Applications (CTA) approvals to the RTOG?

No. Investigators participation in an EU country will be required to provide the CTSU with their Ministry of Health approval letter.

For trials involving a Investigational Medicinal Product (IMP), does a copy of the manufacturing and import authorization license of the importing facility still need to be emailed to RTOG?

No, a copy of the Manufacturing and Import Authorization License of the importing facility must be provide to the CTSU Regulatory Office.

Where can you find the CTSU IRB Transmittal Form and IRB Certification Form in the CTSU web site?

These forms are available on the CTSU Website:

- Open the public side of the CTSU Website
- Select the Regulatory tab
- The forms are located under the "Printable CTSU Forms" section



The CTSU IRB Certification form requires our Federal Wide Assurance (FWA) number. Which assurance number are you requesting - our site's or our IRB's?

The CTSU requires the Federal Wide Assurance (FWA) number of the site.

When do I need to send a Continuing Review for a trial that is closed to accrual?

Per U.S. Federal Regulations, sites are required to obtain continuing review on closed studies until all local patients have completed all treatment and follow up and the study is closed with the local ethics board, or the sponsor indicates they are closing the study to further data collection and follow up. The Lead Group will determine if the Continuing Review is submitted to the CTSU for tracking purposes or kept locally and reviewed at time of audit. To verify if the Lead Group is requiring you to submit your renewals for a closed study to the CTSU, please follow the following steps:

- Log on to the CTSU Members' Website
- Click on the Regulatory Tab
- Click on the Site Registration Tab
- Enter your Institution's NCI code into the Site Number field.
- Enter the protocol code in the Protocol field (or use the Pick button to select the Protocol you are interested in)
- Click Go.

Under the "Registration Status" column you will see the Group Protocol Status of Closed or Closed, Cont Rvw:

- Place your cursor over the protocol's registration status and a question mark along with a window will appear
- If it states Closed, then "no further Continuing Reviews will be collected at the CTSU Regulatory Office" will appear.
- If it states Closed, Cont Rvw, then "Protocol is Closed to Accrual, but IRB Continuing Review is being collected in RSS" will appear.

When submitting yearly renewals, is a consent form submission required?

CTSU sites do not need to send consents to the CTSU for annual renewals.

How can I determine if an amendment approval should be submitted to the CTSU?

The Lead Group will determine when they would like the CTSU to collect the regulatory approval of amendments. This information will be included in the amendment notification release by the Lead Group.

You can also verify this information via the CTSU Website, by following the below steps:

- Logging in to the CTSU Members' Website
- Select the Regulatory tab
- Select the Protocol Reg (requirements) tab



- Enter the protocol code in the Protocol field (or use the Pick button to select the Protocol you are interested in)
- Click Go.

When submitting amendment approvals, is a consent form submission required?

RTOG will determine if the submission of an updated consent form is required when an amendment is set up for collection in RSS. A list of all the requirements set up for collection for a trial will be posted on the CTSU Website.

When preparing RSS paperwork, the IRB Certification Form asks for the protocol version date. On the cover sheet of the protocol that I am using, the protocol lists the current date as the "Activation" date. However, on the bottom left corner of the cover sheet, there is a different date that says "NCI version date". Also, on another protocol, there is a "Version" date as well as an "Update" date. Which date should I put in the on the IRB Certification Form?

Please use the NCI version date on the IRB Certification Form.

How can I see what my approval status is?

You can check your site's approval status for any studies entered into the RSS by:

- Log on to the CTSU Members' Website
- Select the Regulatory tab
- Select the Site Registration tab
- Enter your Institution's NCI code into the Site Number field.
- If desired, modify your search by Registration Status and Protocol number
- Click Go

The CTSU Website will then display all of the protocols that have been entered into the RSS that meet the parameters identified. The second column, Registration Status will indicate current status of the study (ex. Approved, Pending, etc.) in our database. The last column Missing Requirements (if applicable) will list any outstanding requirements that need to be submitted to the CTSU. Please note: if an IRB approval was just recently submitted and updated by our office the last column will indicate IRB Renewed.

How can I find the Investigator NCI number?

Call the CTSU Help Desk at 1-888-823-5923, email the CTSU at cTSUContact@westat.com or search for this information on the CTSU Website.

- Logging in to the CTSU Members' website
- Select the Regulatory tab
- Select the CTEP ID Search tab
- Enter the person's first and/or last name in the name fields
- Click Search

How can I find the NCI Institution Code?

Call the CTSU Help Desk at 1-888-823-5923 or email the CTSU at CTSUContact@westat.com.



Will utilizing the CTSU Regulatory Office affect how I submit my clinical trial data for a trial?

No. Your data forms (CRFs) will still be submitted directly to RTOG.

My site just closed a study locally, what do I need to send to the CTSU Regulatory Office?

For RTOG Lead Studies, the CTSU follows the process outlined in RTOG's Early Closure Broadcast released on June 3, 2010. Per RTOG's Policy:

- Sites will be required to complete the RTOG Study Closure Form and submit the document directly to RTOG.
- RTOG will verify the site is permitted to withdraw from the study. If permitted, RTOG will sign the RTOG Study Closure Form and send the document back to the site.
- To withdraw the site in RSS, the CTSU Regulatory Office will require that the site to submit local
 documentation stating the RTOG study has been closed at their institution and a copy of the
 signed RTOG Study Closure Form.