

Training Resources

SWOG Training Resources List for Oncology Research Professionals:

<https://www.swog.org/media/13452>

Training Resources – SWOG Learning Management System

Website	System	Function
<p>SWOG.org (https://swog.exphosted.com)</p> <p>- Login with CTEP credentials</p> <p><i>First time LMS access:</i></p> <ul style="list-style-type: none"> • Please see CTTC Access Instructions for general LMS system access instructions. 	<p>ExpertusOne</p>	<p>SWOG-member-only Training</p> <ul style="list-style-type: none"> • Clinical Trials Training Course (CTTC) • SWOG Oncology Research Professionals Regulatory Workshop • Study Chair Workshop • Early-Stage Investigator Workshop (Online portion) • Investigational Agent Handling • TeamScience for SWOG Members • Enduring CME Courses (provided by The Hope Foundation): <ul style="list-style-type: none"> • Advanced Practice Provider Clinical Research Workshop • Role of Surgery and Radiation in Metastatic Prostate Cancer • The Role of Nephrectomy in Advanced Renal Cancer • ...regular content additions!**

** As new training opportunities and SWOG-generated materials become available, announcements are posted at: [Announcements/ Current Training Opportunities | SWOG](#)

****New**** Lead ORP Workshop ~ Modules

- SWOG Lead Oncology Research Professional (Lead ORP) Workshop:
 - **Introductory Modules**
 - [SWOG Lead Oncology Research Professional Workshop Introduction](#) (10 mins)
 - [SWOG and NCI: An Introduction](#)
 - **Leadership and Site Operations Modules**
 - [Leadership Perspective](#) (17 mins)
 - NCI Trials - Site Operations Perspective (forthcoming modules)
 - Site-level feasibility assessment
 - Site-level activation processes
 - Institutional Roles
 - Collaboration with the SWOG Site PI
 - Tips, Tricks, and Tools
 - **SWOG and NCI Systems Module**
 - [SWOG and NCI Systems Overview Training](#) (14 mins)
 - **Data Management and Resource Access Modules**
 - [Data Management and Access Module Introduction for Lead ORPs](#) (1 min)
 - [CTSU Website Overview](#) (9 mins)
 - [SWOG Website Overview](#) (4 mins)
 - [SWOG CRA Workbench Overview](#) (4 mins)
 - [iMedidata RAVE Access for Lead ORPs](#) (6 mins)
 - [SWOG Specimen Tracking System for Lead ORPs](#) (8 mins)
 - [Central Monitoring](#) (5 mins)
 - **Funding and Site Payments Modules**
 - [NCTN and NCORP Study Funding and Payment Distribution](#) (20 mins)
 - [Open Funding](#) (10 mins)
 - [National Coverage Analysis Overview](#) (4 mins)
 - **Study Activation and Management Modules**
 - [Delegation of Tasks Log](#) (2 mins)
 - [Adverse Events Training for Lead ORPs](#) (8 mins)
 - [Dose Modifications Training for Lead ORPs](#) (1 min)
 - [Serious Adverse Event Reporting Training for Lead ORPs](#) (30 mins)
 - [SAE Reporting - Specific Exceptions to Expedited Reporting for Lead ORPs](#) (4 mins)
 - [Data Entry in Difficult Situations Training for Lead ORPs](#) (2 mins)
 - [Record Retention Training for Lead ORPs](#) (3 mins)
 - **Reports and Tools for Data Quality Modules**
 - [Expectations and Expectation Reports for Lead ORPs](#) (10 mins)
 - [Vital Status Expectations Training for Lead ORPs](#) (5 mins)
 - [Specimen Expectations Training for Lead ORPs](#) (8 mins)
 - [Institution Performance Review Training for Lead ORPs](#) (10 mins)
 - [Query Reports Training for Lead ORPs](#) (4 mins)
 - [CTSU reports - Data Quality Portal \(DQP\) Training for Lead ORPs](#) (7 mins)
 - **Regulatory Module**
 - [Regulatory Expectations from a QA Perspective - Training for Lead ORPs](#) (13 mins)
 - **Quality Assurance Modules**
 - [Audits and Quality Assurance Program - Training for Lead ORPs](#) (20 mins)
 - [Protocol Deviations vs. Deficiencies Training for Lead ORPs](#) (4 mins)
 - [When is my Institution's next Audit Due? - Training for Lead ORPs](#) (2 mins)

SWOG (ExpertusOne)

Learning Management System (LMS)

- Direct link to the LMS is located on the SWOG Member-side of the website under the “Member Resources” menu,
 - Or, via direct url: <https://swog.exphosted.com>.
 - Login with CTEP IAM credentials required to access.
- SWOG Member Training Courses, plus
 - Brief (5-15 minutes) modular course additions ongoing.
 - For short courses, filter by
- SWOG study-specific training is maintained in the [CTSU Compliance, Learning, and SOP Solutions \(CLASS\) Learning Management System \[CTSU CLASS LMS\]](#); Accessible NCTN-wide to staff with CTEP IAM login.

Clinical Trials	Member Resources
Advocate Resources	
BMT Facility List	
Breast Cancer Commons	
CRA Workbench	
Digital Engagement	
Hope Funding Opportunities	
Membership	
Oncology Research Professionals	
Pharmaceutical Sciences	
Protocol Tracking Reports	
Publications & Presentations	
Radiation Therapy Facility List	
Recruitment & Retention	
Report of Studies	
Safety Reports	
Study Chair Workbench	
Training for SWOG Members	



SWOG has launched a new Learning Management System (LMS)!

THE EXPERTUSONE LMS WILL BE HOME TO ALL TRAINING THAT IS SPECIFIC TO SWOG MEMBERS.

- ✓ **Training certificates** are viewable and printable for one year after completing a course.
- ✓ **Courses are available** in brief 5- to 15-minute modules.
- ✓ **Content is regularly added** and updated. See the “Announcements” window for new content.
- ✓ **In a user-friendly interface**, you can view trainings, take surveys, and complete assessments all from one LMS content player – also available for mobile devices.
- ✓ **Allows us to host** virtual classes integrated with WebEx or Zoom.

NCTN-wide training — such as for protocol-specific requirements and PRO training — will remain in the CTSU CLASS system. But SWOG internal training for members and staff will be in ExpertusOne.

Some of the training content now within ExpertusOne:

- Study Chair Workshop
- Young Investigator Workshop Online
- Investigational Agent Handling
- Clinical Trials Training Course
- Team Science

Access SWOG's new LMS at swog.exphosted.com, or link from the “Training for SWOG Members” item on the “Member Resources” menu. Use your CTEP IAM credentials to log in.

swog.exphosted.com


www.expertusone.com

SWOG (ExpertusOne) Learning Management System (LMS)

- The SWOG Learning Management System Catalog is set-up for voluntary course enrollment, by SWOG membership type.
- Under the Catalog “Filters”: Members can search for classes by key search term (e.g., data submission, reports, specimen, etc.), by “Training Type”, or by language.
- SWOG is in the process of adding Spanish language courses to the LMS. To search for courses available in Spanish, de-select “English” under “Language and select “Español”.

SWOG CANCER RESEARCH NETWORK | **THE HOPE FOUNDATION** FOR CANCER RESEARCH

MY LEARNING | MY DASHBOARD | **CATALOG** | MY PROFILE

CATALOG ALL (22) WISHLIST (0)

Shows all the latest and relevant Courses/Certifications/Learning Paths that you can enroll for. Results for the search are shown if the keyword you provide matches with the title, code, description, tag or category associated with the training.

SEARCH [] [] FILTERS [] SORT []

CATEGORY

TYPE CATEGORY [] []

- Data Submission and Reports
- Ethics
- Investigational Agent Handling
- Investigators
- ...

TRAINING TYPE

- Course
- Certification
- Learning Path

LANGUAGE

TYPE LANGUAGE [] []

- English
- Español

RATING

- ★★★★★
- ★★★★☆
- ★★★☆☆
- ★★☆☆☆
- ★☆☆☆☆

Filters:

- For short courses, filter by “Training Type” >> “Course” (5-20 minutes)
- For complete member training plans, filter by “Training Type” >> “Learning Path”.
- For courses with available CEU credits, filter by “Training Type” >> Certifications.

Note “Learning Paths” and “Certification” courses are set up for completion within 6 months after the date of enrollment. If Learning Path is not completed within 6 months, members will receive an occasional “Overdue” reminder notice.

SWOG (ExpertusOne) Learning Management System (LMS)

- After enrolling in a course, certification, or learning path, the training content will appear under the “My Learning” section.
- From the “My Learning” section, you can:
 - View course progress,
 - Launch the training content,
 - Launch the course assessment,
 - Bookmark content that you find helpful (for ease of subsequent review after completion),
 - Share (via email or messaging system) the content with a colleague, or
 - Cancel your enrollment to the course.
- If you click on the picture or title portion of the course, it will take you to a detail screen, where you can select and enroll in the available classes in the course or Learning Path.

The screenshot shows the 'MY LEARNING' dashboard. At the top, there are logos for SWOG Cancer Research Network and The Hope Foundation for Cancer Research. Navigation links include 'MY LEARNING' (highlighted with a red box), 'MY DASHBOARD', 'CATALOG', and 'MY PROFILE'. Below the navigation is a search bar and a 'FILTERS' button. A summary section shows 'TO-COMPLETE (29)', 'COMPLETED (21)', and 'ALL (50)' (all three are highlighted with a red box). The main area displays four course cards. Red callouts point to specific icons: 'Share icon' (a share symbol), 'Bookmark icon' (a bookmark symbol), 'Cancel Enrollment Icon' (an 'X' in a square), and 'Take Assessment icon' (a play button symbol). A red box at the bottom of the first card contains the text 'To launch a course, click on the Play icon' with an arrow pointing to the play button. A 'SHOW ALL' button is visible at the bottom right of the course grid.



1 . INVESTIGATIONAL AGENT HANDLING INTRODUCTION

Investigational Agent Handling Introduction

CODE : IAH-INTRO.01 | CONTACT SUPPORT : Not Available | Required | Yet To Select Class

[VIEW CLASSES](#)



2 . INVESTIGATIONAL AGENT HANDLING PROCUREMENT

Investigational Agent Handling Procurement

CODE : IAH.PROCURE.01 | CONTACT SUPPORT : Not Available | Required | Yet To Start

[HIDE CLASSES](#)



INVESTIGATIONAL AGENT HANDLING PROCUREMENT

Investigational Agent Handling Procurement

0%

Yet to Start

READ

Class Code	: IAH.Procure.01
Language	: English
Provider	: Internal
Enrolled by	: Self
Enrolled on	: Apr 18, 2023
Contact Support	: Not Available

TAKE ASSESSMENT

- This is an example of the course detail screen where you can view classes, select or launch a selected class, view class progress, and take the assessment (subsequent completion of the class content) associated with each class.
- After completion of the class, a “Completion Certificate” link will appear next to the “Take Assessment” link, where you can download a completion certificate for the class.

LAUNCH

SWOG (ExpertusOne) Learning Management System (LMS)

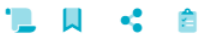
TO-COMPLETE (29) COMPLETED (21) ALL ()

PROTOCOL DEVELOPMENT



PROTOCOL DEVELOPMENT FOR INVESTIGATORS

WATCH



COMPLETED



COMPLETED ON
FEB 13, 2023



1 . PROTOCOL DEVELOPMENT FOR STUDY CHAIRS

Protocol Development for Study Chairs

CODE : SC.PD.01 | CONTACT SUPPORT : Not Available | Required | Completed

HIDE CLASSES



PROTOCOL DEVELOPMENT FOR INVESTIGATORS

Protocol Development for Investigators

WATCH

Class Code : INV.PD.01
Language : English
Provider : Internal
Enrolled by : Self
Enrolled on : Mar 20, 2023
Completed By : Cara Laubach
Completed On : Feb 13, 2023
Contact Support : Not Available

100%

Completed

COMPLETION CERTIFICATE TAKE ASSESSMENT

LAUNCH

Attachments : None

To access the course detail screen after completion of the course:

- Go to “My Learning” >> select the “Completed” tab >> then click on the picture or title of the course.

SWOG (ExpertusOne) Learning Management System (LMS)

- After completion of a course or entire training plan, the course completion certificate will also be available for download from the “My Certificates” section of the dashboard. Certificates are available for download for 1 year after completion of the training.

To access the “My certificates” screen:

- Go to “My Dashboard” >> scroll right >> “My Certificates” >> then select either the “Course” or “Learning Path / Certification” tab to view certificates.

The screenshot displays the SWOG LMS dashboard. At the top, the SWOG logo (Cancer Research Network) and The Hope Foundation logo (For Cancer Research) are visible. Navigation links include 'MY LEARNING', 'MY DASHBOARD' (highlighted with a red box), 'CATALOG', and 'MY PROFILE'. The main dashboard area features four cards: 'LEARNING HISTORY' (63), 'MY CERTIFICATES' (21, highlighted with a red box), 'LEARNING PLAYLISTS' (0), and 'POINTS' (0). Below this is the 'MY CERTIFICATES' section, which includes a filter for 'From' and 'To' dates (format: MMM DD, YYYY) and an 'APPLY' button. Two tabs are present: 'COURSE' (highlighted with a red box and an arrow) and 'LEARNING PATH / CERTIFICATION'. Below the tabs, a certificate entry is shown for 'REGISTRO EN CITI', completed on Sep 02, 2022, with a score of 0. A 'VIEW CERTIFICATE' link is located to the right of the entry.

Training and Related Resources – SWOG website

Website	Resource Topic
SWOG.org	<ul style="list-style-type: none">• SWOG CRA Workbench<ul style="list-style-type: none">• SWOG VA Workbench• SWOG Policies and Procedures• SWOG Announcements and Current Training Opportunities• SWOG Clinical Research Resources<ul style="list-style-type: none">• SWOG Oncology Research Professionals Resources• SWOG Data Submission Guidance, Tips, and Tricks• Oncology Research Professionals Committee Webpage• SWOG Frequently Asked Questions• SWOG Quality Assurance and Audits• SWOG Protocol Workbench<ul style="list-style-type: none">• Serious Adverse Event Reporting• SWOG Biospecimen Processing and Submission Procedures• Patient-Reported Outcome Questionnaires Training

SWOG Quality Assurance, Auditing and Monitoring Resources

- The publicly accessible SWOG “Quality Assurance and Audits” webpage includes a collection of regulatory and accountability resources pertinent to responsible research conduct of SWOG (and NCTN) clinical trials.
- In particular, note links to:
 - [SWOG Regulatory Guidance, July 2021](#)
 - A guide to successful regulatory audit.
 - [SWOG Quality Assurance Audit Guidelines](#)
 - Guidance documents for regulatory documentation and preparation for FDA inspection and FDA registration trials:
 - [Trial Master File](#)
 - [Investigational Drug Accountability](#)
 - [SWOG Best Practices](#) guidance document (allowable treatment/procedure windows, specimen collection and submission, consent scenarios)
 - [Patient Chart Review](#) guidance document
 - [Record Retention Guidance](#)

The screenshot shows the SWOG Cancer Research Network website. The top navigation bar includes 'About', 'The SWOG Network', 'News & Events', and 'Clinical Trials'. A dropdown menu is open under 'Clinical Trials', listing various resources. A red arrow points to the 'Quality Assurance & Audits' option. Below the dropdown, the 'Quality Assurance & Audits' page content is visible, including a 'VIEW' button, a 'Quality Assurance & Audits' section, and a list of resources: SWOG Policy 19: Quality Assurance Program, SWOG Quality Assurance Audit Guidelines, and NCI-CTMB Guidelines for Monitoring of Clinical Trials, effective 1/1/2018. A 'Regulatory Guidance' section is also present, stating that clinical trials operate under the policies and regulations of the federal Office for Human Research Protections (OHRP).

SWOG.org Clinical Research Resources – Regulatory References

- [Clinical Research Resources | SWOG](#)
 - Webpages devoted to onboarding resources and continuing education
 - Specifically, the [Clinical Research and Human Research Protection Training | SWOG](#) and [Regulatory and Ethical Research Conduct References | SWOG](#) pages contain a wealth of regulatory resources, such as:
 - Pertinent NCI and CIRB links, such as the [NCI Investigator's Handbook](#)
 - OHRP [Office of Human Research Protections Human Subjects Protection Training](#)
 - [CMS HIPAA Basics for Providers](#) guidance document
 - [DHHS HIPAA for Professionals: Special Topics: Research](#)
 - [HIPAA FAQs database for Professionals](#)
 - NIH Introduction to the Principles and Practice of Clinical Research (IPPCR)
 - Module 1 includes Research Ethics, FDA Product Regulation and Legal Issues in Clinical Research
 - Module 5 addresses Institutional Review Boards
 - [FDA Overview of Drug Development](#) (non-clinical safety assessment perspective)
 - [FDA Oncology Drug Development Overview – Past to Present](#)
 - [FDA Regulations: Good Clinical Practice and Clinical Trials](#)
 - [FDA Clinical Trials and Human Subject Protection](#)
 - Most recent clinical research guidance document updates
 - FDA comprehensive list of [Clinical Trials Guidance Documents](#)
 - [NIH NIAID ClinRegs](#): Aggregated summary of clinical research regulations by topic area

SWOG.org Frequently Asked Questions Webpages

The screenshot shows the SWOG.org website navigation menu at the top, with 'Clinical Trials' highlighted in a red box. Below the menu, a text box states: 'The FAQs web pages provide SWOG-specific information and address the most common site questions.' The main heading is 'Frequently Asked Questions'. A list of FAQ topics is provided, including 'Adverse Events, Serious Adverse Events, and External Safety Reports', 'Quality Assurance', 'Protocol Conduct', 'Data Submission', 'Funding, Financial Agreements, and Study Payments', and 'SWOG Membership'. On the right side, a vertical navigation menu lists various resources, with 'Frequently Asked Questions' highlighted in a red box.

About The SWOG Network News & Events **Clinical Trials**

Biospecimen Resources
Clinical Research Resources
Clinical Trials Search
Frequently Asked Questions
Publications
Institutions
Quality Assurance & Audits
Serious Adverse Events
Training Resources
CRA Workbench
Protocol Workbench

The FAQs web pages provide SWOG-specific information and address the most common site questions.

Frequently Asked Questions

- [Adverse Events, Serious Adverse Events, and External Safety Reports](#)
- [Quality Assurance](#)
- [Protocol Conduct](#)
- [Data Submission](#)
- [Funding, Financial Agreements, and Study Payments](#)
- [SWOG Membership](#)

Training Resources – SWOG CRA Workbench

Website	System	Resource Topic
<p>SWOG.org</p> <p>- Login with CTEP credentials</p>	<p>CRA Workbench</p>	<ul style="list-style-type: none">• ORP Manual• Additional training information <p>Other resources</p> <ul style="list-style-type: none">• General resources• Calculators and other tools• CRA Newsletter• CRA Resources

CRA Workbench

Popular Resources

OPEN Patient Registration

Rave Data Submission

Specimen Tracking ★

SWOG QA / Audits / Monitoring

SWOG Best Practices ★

New CRA Training

Tools +

Resources +

★ CRA Manual (for Oncology Research Professionals) +

★ Patient Reports / Data Quality +

★ Study Reports +

★ Patient Management (Non-Rave Studies) +

★ Training +

★ Contact Us

Find ORP Resources on the CRA Workbench

Your resource headquarters for SWOG clinical trial patient management.

Announcements

- “Studies with no required follow-up” is a report of studies that can be terminated with the IRB of record.



SWOG CRA Workbench

- Login with CTEP IAM credentials required to access
- CRA Manual for ORP
- Expectation, IPR and Query Reports
- Recent updates: “Announcements” and the Quarterly “CRA Newsletter”
- Helpful SWOG and CTSU Contact Information

Study Reports	-
Studies with no required follow-up	★
Studies in Long Term Follow-up	
SAEs for a Study	
S0820 Potential Patients	
Study-wide Unblinding	
Accrual by Site	
Accrual by Race and Sex	
Accrual by Disease Committee	
BMT Facilities	
RT Facilities	

Training	-
SWOG Clinical Trials Training Course (CTTC)	
Your First Group Meeting	
★ Every CRA Should Know... ★	

Tools	-
BSA Calculator	
Clinical Trial Review Guide	
COVID Protocol Deviation Log (Word)	
COVID Protocol Deviation Log (PDF)	
Creatinine Clearance Calculator	
Date Counter	
Ideal Body Weight Calculator	

Patient Reports / Data Quality	-
★ Expectations	
★ Institution Performance Review (IPR)	
★ Queries (both Rave and pre-Rave SWOG studies)	
Ineligible Patients	
Patients in Follow-up	
Data Quality Portal (DQP) for Rave studies	

Contact the Statistics and Data Management Center (SDMC)
★ Contact Reference Sheet



Training Resources – CTSU CLASS LMS

Website	System	Function
CTSU.org CTSU CLASS Learning Management System (under the CLASS tab)	CLASS	<ul style="list-style-type: none"> • SWOG Study-specific Training • NCI Systems Training (e.g., Aurora, SDP) • Other Group’s Training / Study-specific Training

CTSU Compliance, Learning, and SOP Solutions (CLASS) Learning Management System

Home Protocols Dashboard Regulatory OPEN Data Management Auditing & Monitoring RUMS Delegation Log Resources Collaboration **CLASS** Reports

My Courses

Welcome to the Compliance, Learning, and SOP Solutions (CLASS) Page

CLASS is the learning management system supported by the CTSU. It delivers several types of training courses, including:

- Protocol-specific trainings (some of which are required for site registration approval)
- Application-specific trainings
- Role or position-specific trainings
- Membership-related trainings

Everybody with an active CTEP-IAM account can access CLASS. Access to certain training courses may be limited by roster membership, roles, and/or IRB approval or site registration.

If you have questions about CLASS, please [contact the CLASS Help Desk](#).

Resource Materials

View the CLASS User Guide [here](#).

[Connect to the CLASS Website](#)

CTSU (CLASS) Example Catalog View

- Note: For ease of access/review in the catalog, the Course Name for all SWOG-provided Study Specific Training begins with “SWOG”

The screenshot displays a web-based course catalog interface. At the top, there is a browser address bar showing the URL <https://classms.org/#/catalog/>. The interface features a grid of course cards, each with a header image, a title, a description, and an action button. The courses are organized into three rows. The first row contains ten cards, all with blue headers and 'Enroll' buttons. The second row contains ten cards, with the first six having blue headers and 'Enroll' buttons, and the last three having green headers and 'Completed' buttons. The third row contains ten cards, all with green headers and 'Completed' buttons. The SWOG courses in the second and third rows all begin with 'SWOG' in their titles. The interface also includes navigation icons at the top left and right, and a search icon.

Course Title	Duration	Status
Alliance Geriatric Assessment Training	21m	Enroll
Alliance: RECIST and iRECIST Training	1h 6m	Enroll
Moonshot: Biomarker Report Training	42m	Enroll
Moonshot: Biospecimen & Kit Training	48m	Enroll
Moonshot: eConsent Training	1h 2m	Enroll
Moonshot: Engagement Website Training	35m	Enroll
Moonshot: IRB Training	56m	Enroll
Moonshot: Protocol & Eligibility Training	54m	Enroll
Moonshot: Rava EDC Training	26m	Enroll
Moonshot: TRIAD Training	54m	Enroll
NCI/CTEP AURORA - Document Access	10m	Enroll
NCI/CTEP AURORA Training Series 1 Version	1h 46m	Enroll
Protocol NCICQVID - New NCCAPS Amendment	16m	Enroll
Source Document Portal (SDP) for Auditors	18m	Enroll
Source Document Portal (SDP) for Central	13m	Enroll
Source Document Portal (SDP) for Safety Ticket	18m	Enroll
Source Document Portal (SDP) for SDP	13m	Enroll
SWOG: How to Conduct the Neuropan Assessment	5m	Completed
SWOG: How to Conduct the Timed Get Up and Go	2m	Completed
SWOG: How to Conduct the Tuning Fork	5m	Completed
SWOG: How to Use the Paxman Limb	48m	Completed
SWOG: S1800D Site Initiation Training	21m	Completed
SWOG: S1900F Site Initiation Training	29m	Completed
SWOG: S2010 Optional Site Initiation Training	20m	Completed
SWOG: S2010 Required PRO Core Software	31m	Completed
SWOG: S2011 Optional Training - Refresher	12m	Completed
SWOG: S2015 Site Initiation Training	12m	Completed
SWOG: S2101 (iMATCH Pilot Study) Site Initiation	19m	Completed
SWOG: S2107 Site Initiation Training	21m	Completed
SWOG: S2108CD Site Initiation Training	50m	Completed

Training Resources – CTSU website

Website	Resource Topic
CTSU.org	<ul style="list-style-type: none">• Help Topics (on most CTSU.org screens)• Resources tab• Frequently Asked Questions

CTSU.org Help Topics

- Help topics appear on most CTSU screens, and have replaced user guides
- They are unique to the screen being viewed
- Clicking the icon shows the drop-down, a link opens the page, which has navigation
- Home help topics give an overview of the entire website

The screenshot shows the CTSU.org Regulatory page. The top navigation bar includes links for Home, Protocols, Dashboard, Regulatory (highlighted), OPEN, Data Management, Auditing & Monitoring, RUMS, Delegation Log, Resources, Collaboration, and Reports. Below this is a sub-navigation bar with Site Registration, Protocol Requirements, Provider Association, and Regulatory Submission (highlighted). The main content area contains text about the CTSU Regulatory Office, search filters for Site Number, Registration Status, Protocol Status, and IRB Type, and a table for Site Registrations. A red box highlights a help icon (a question mark) in the top right corner, which is linked to a dropdown menu of help topics. A red arrow points from the help icon to the dropdown menu.

The CTSU Regulatory Office is available to answer your regulatory questions by phone (1-866-651-2100) or email CTSURegHelp@coocg.org. If you have a subject waiting, be sure to submit your regulatory documents as urgent via the Regulatory Submission Portal and you will be contacted once your submission has been processed.

Site Number: Registration Status: Protocol Status: IRB Type:

Protocol: [Disclaimer](#)

[Site Registrations](#)

#	Site	Protocol Number	LPO	Protocol Status	IRB Type	IRB Approval Expiration (Days)	CTSU Collecting IRB Continuing Review?	Member Of LPO or PO	Site-Protocol PI	Site Registration Status	M
No records were found that matched the criteria											

Help Topics:

- [Site Registration](#)
- [Protocol Requirements](#)
- [Provider Association](#)
- [Regulatory Submission](#)
- [CIRB Site Preferences](#)
- [CTSU Forms](#)
- [Resources](#)
- [Regulatory Contacts](#)

CTSU.org Resources

- Resources > CTSU Operations Information > General Procedures and Training, contains introductory materials
- Tips for Onboarding and Site Staff Orientation Slides are geared for new site staff

The screenshot shows the CTSU.org Resources Browser interface. The top navigation bar includes links for Home, Protocols, Dashboard, Regulatory, OPEN, Data Management, Auditing & Monitoring, RUMS, Delegation Log, Resources (highlighted with a red box), Collaboration, CLASS, and Reports. The left sidebar, titled 'Resources Browser', contains a search bar and a tree view of categories. The 'CTSU Operations Information' category is expanded, and 'General Procedures & Training' is selected. The main content area displays a table of documents under the heading 'General Procedures & Training'. The table has columns for '#', 'Title', 'Format', and 'Post Date'. A red box highlights the 'CTSU Operations Information' category in the sidebar. A red box highlights the 'General Procedures & Training' category in the table. A red arrow points to a star icon next to the title 'CTSU Overview PowerPoint Presentation', with the text 'add to your favorites' next to it. A red box highlights the row for 'New Site Staff and the CTSU: Tips for Onboarding'. A red box highlights the 'Site Staff Orientation Slides' section, which contains four rows of modules. The text '10 modules' is written in red next to the first row of this section.

#	Title	Format	Post Date
Basic Processes			
1	Access Rules ★	Web Link	24-Jun-2021
2	CTSU Overview PowerPoint Presentation ★	PDF	13-Sep-2021
3	Getting Started with the CTSU ★	PDF	20-Jul-2022
4	New Site Staff and the CTSU: Tips for Onboarding ★	Web Link	26-Jul-2022
5	Participation and Crediting Rules ★	Web Link	15-Jan-2021
6	Regulatory: Introduction and Overview ★	PDF	03-Aug-2021
Site Staff Orientation Slides			
1	Module 01: Introduction ★	PDF	29-Sep-2021
2	Module 02: Person Registration ★	PDF	25-Jul-2022
3	Module 03: Roster Maintenance and Roles ★	PDF	29-Sep-2021
4	Module 04: CTSU Website ★	PDF	29-Jul-2022

CTSU.org Researcher Resources

- Resources > Researcher Resources, contains resource links to policies, guidelines, and training materials relevant to conduct of NCI research trials.

The screenshot displays the CTSU.org Resources Browser interface. The top navigation bar includes links for Home, Protocols, Dashboard, Regulatory, OPEN, Data Management, Auditing & Monitoring, RUMS, Delegation Log, Resources, Collaboration, CLASS, and Reports. The 'Resources' dropdown menu is open, showing a list of categories with 'Researcher Resources' highlighted in a red box. A red arrow points from the 'Resources' dropdown to the 'Researcher Resources' section in the main content area. The left sidebar contains a search bar and a tree view of resource categories, with 'Researcher Resources' also highlighted in a red box. The main content area displays a table of resources under the heading 'Researcher Resources'.

#	Title	Web Link	Last Updated
Adverse Event Reporting and CTEP-AERS			
1	Common Terminology Criteria for Adverse Events (CTCAE) ★		
2	CTEP-AERS Training Guide ★		
3	FDA Form 3500 (MedWatch) ★		
4	NCI CTEP Adverse Event Reporting System (CTEP-AERS) : Links to application, templates, and instructions. ★		
Audit Resources			
1	CTMB Audit Guidelines ★		
Dangerous Goods Shipping Training			
1	Dangerous Goods International (DGI) Institute ★	Web Link	23-Mar-2017
2	Saf-T-PAK, Inc. Training Course ★	Web Link	23-Mar-2017
Human Subjects Protection			
1	NIH - Tutorial on Human Participant Protections Education for Research Teams ★	Web Link	28-Aug-2018
2	U.S. Dept. of Health and Human Services Office for Human Research Protections ★	Web Link	10-Jul-2017
IRB and Assurance Information			
1	Federalwide Assurance (FWA) ★	Web Link	23-Mar-2017
2	IRB Registration ★	Web Link	23-Mar-2017
National Cancer Institute Resources			

CTSU.org Frequently Asked Questions

- Resources > FAQs

The screenshot displays the CTSU.org website interface. At the top, a navigation bar includes links for Home, Protocols, Dashboard, Regulatory, OPEN, Data Management, Auditing & Monitoring, RUMS, Delegation Log, Resources, Collaboration, CLASS, and Reports. The 'Resources' link is highlighted with a red box. Below the navigation bar is the 'Resources Browser' section, which features a search bar and a list of subfolders. The 'Frequently Asked Questions (FAQs)' subfolder is highlighted with a red box and contains a list of topics such as 'Show All', 'Audit', 'Awareness, Education & Training', 'CTSU Members Website', 'CTSU Membership', 'CTSU National Coverage Analysis (NCA) Initiative', 'Data Quality Portal (DQP)', 'Data Submission', 'Delegation of Tasks Log (DTL)', 'National Clinical Trials Network (NCTN)', 'Oncology Patient Enrollment Network (OPEN)', 'Patient Enrollment', 'Protocols', 'Rave', 'Regulatory - CIRB', 'Regulatory - General', 'Regulatory - local IRB', and 'Source Document Portal'. To the right of the browser is the 'Resources' content area, which provides an overview of the section and includes a 'feedback button' link. A red arrow points from the 'Resources' menu item to the 'Frequently Asked Questions (FAQs)' subfolder.

Home Protocols Dashboard Regulatory OPEN Data Management Auditing & Monitoring RUMS Delegation Log Resources Collaboration CLASS Reports

Resources Browser

Search by Document Title

Enter search term Go!

- + My Protocols
- + My Favorites [0 docs]
- + Experimental Therapeutics Clinical Trials Network (ETCTN) Program
- + CTSU Operations Information
- + Researcher Resources
- + Educational Multimedia
- + Site Advisory Panel
- + Translated Short Form Consents
- + Disease Portfolios
- + Protocol Specific Materials
- Frequently Asked Questions (FAQs)
 - Show All
 - Audit
 - Awareness, Education & Training
 - CTSU Members Website
 - CTSU Membership
 - CTSU National Coverage Analysis (NCA) Initiative
 - Data Quality Portal (DQP)
 - Data Submission
 - Delegation of Tasks Log (DTL)
 - National Clinical Trials Network (NCTN)
 - Oncology Patient Enrollment Network (OPEN)
 - Patient Enrollment
 - Protocols
 - Rave
 - Regulatory - CIRB
 - Regulatory - General
 - Regulatory - local IRB
 - Source Document Portal
- Glossary and Acronyms

Resources

The Resources section of the CTSU website has education and training materials available to assist in the conduct of clinical trials. The Resources Browser on the left side of your screen aids in finding these materials by providing access to a wide range of materials and information. The Resources Browser on the left side of your screen aids in finding these materials by providing subfolders that further organize the content of each section.

For detailed information on the content contained here, select the Help Topics icon to the right, the drop-down correlates the content to the Help Topics. Use the [feedback button](#) to submit any questions or concerns you may have regarding website Resources.