



TIPS AND TOOLS FOR WORKING WITH THE CTSU

SWOG Group Meeting
Oishi Symposium

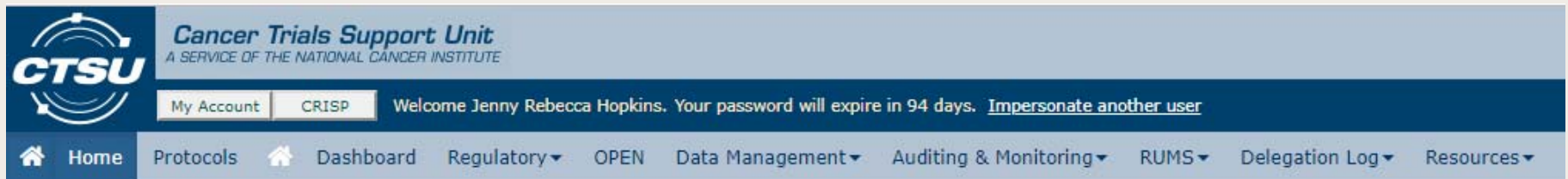
Jenny R. Hopkins, CTSU Assistant Project Director

Topics

- Maximizing the CTSU Website
- Rostering Tips
- Viewing Regulatory Information
- Data Quality Portal Reminders and Tips
- CTSU Dashboard
- CRISP Notifications
- General Resources






Maximizing the CTSU Website

- The CTSU has a robust website that serves as the center point for many of the activities sites perform with respect to the conduct of NCI-funded clinical trials.
- These are some tips and tricks that apply across the website, as well as some that are more context-specific.
 - The goal is to help those using the website to become more *efficient* and *self-sufficient* and minimize the need to contact the CTSU Help Desk.





The screenshot shows the top navigation bar of the CTSU website. On the left is the CTSU logo, a circular emblem with the letters 'CTSUS' inside. To its right, the text reads 'Cancer Trials Support Unit' in a bold, dark blue font, with 'A SERVICE OF THE NATIONAL CANCER INSTITUTE' in a smaller, lighter blue font below it. Further right, there are two buttons: 'My Account' and 'CRISP'. To the right of these buttons is a user greeting: 'Welcome Jenny Rebecca Hopkins. Your password will expire in 94 days. [Impersonate another user](#)'. Below this bar is a horizontal navigation menu with several items: 'Home' (with a house icon), 'Protocols', 'Dashboard' (with a house icon), 'Regulatory' (with a dropdown arrow), 'OPEN', 'Data Management' (with a dropdown arrow), 'Auditing & Monitoring' (with a dropdown arrow), 'RUMS' (with a dropdown arrow), 'Delegation Log' (with a dropdown arrow), and 'Resources' (with a dropdown arrow).

Things to Look For on the Website


- Click on  or  on most pages/applications to find details on their use (i.e., user guide-type content).
- Use  buttons to display context-specific details.
- Use *More Commands*  or *Export to Excel*  buttons to export tables/grids for review and distribution.
- Use filters to focus your queries and reports.
- Use the Dashboard for information that is personalized to you and your site(s).
- Use CRISP to subscribe to email notifications.

Page-Specific Help Content

- Help Topics 
 - Home Page
 - Regulatory
 - Source Document Portal
 - RUMS
 - Delegation Log
- Other help content, incl. user guides or 
 - Dashboard
 - OPEN
 - Data Management, incl. DQP
 - CRISP

Person Information (Including Your Own)

Click on the My Account button to access information about your account

Use the Person  button to view affiliation and registration data (all persons)

Do you receive the Bi-Monthly Broadcast?

Expiration dates and registration type

Hopkins, Jenny (500178)			
Name	Hopkins, Jenny	CTEP ID	500178
Primary Site	WESTAT	Site Name	WESTAT
NCI Registration Status	Active	NCI Registration Type	AP
NCI Registration Expiry	10/06/2019		

CONTACT INFO	
Email	jennyhopkins@westat.com
Office phone	[REDACTED]

ADDRESSES	
Office (CTEP):	Ms. Jenny Rebecca Hopkins [REDACTED]

ACTIVE MEMBERSHIP						
Network Group	p	Site CTEP #	Site Name	Study Type	Status	Date
All Organizations of which you are a member will show as well as each site you are rostered to (for each organization).						

PRACTICE SITES			
CTEP ID	Name	Status	Status Date
No Practice Site information available.			
This information will show for Investigators and Non-Physician Investigators.			

IRBS			
IRB Number	Name	CIRB	Status
No IRB information available.			
This information will show for Investigators and Non-Physician Investigators.			

DOCUMENTS	
Registration Document Type	
GCP	Can hyperlink directly to these documents within the Registration and Credential Repository (RCR).
HSP	
NCI Blasketch	

TRAINING			
Course Title	Training Institution	Completion Date	Expiry Date
Human Subjects Protection Training	Westat	10/01/2016	
GCP/ICH Obligations of Sponsors, Monitors, and Investigators	Westat	01/01/2017	01/01/2020

Tips for Rostering in RUMS

- Review the Help Topics
 - Includes the rostering business rules and roles and access matrix (by organization)
- Use the browser filters to run reports

Help Topics

- [Overview](#)
- [Application Access](#)
- [RUMS Integrations](#)
- [RUMS Business Rules](#)
- [Managing RUMS Requests](#)
- [Resources](#)
- [Roles & Access](#)

Person Roster Browser | Org Roster Browser | CTEP ID Search | Tracking

SWOG | KS004 | Rave CRA | All Registration Types | All Persons | All CTEP Statuses

Change page: [Navigation icons]

Person Name	Registration Type	CTEP ID	CTEP Status	Registration Expiry Date	Site	Roster Status	Roles
[Redacted]	Associate Plus	[Redacted]	Active	17-Sep-2019	KS004	Active	Rave CRA
[Redacted]	Associate Plus	[Redacted]	Active	04-Aug-2020	KS004	Active	Rave CRA
[Redacted]	Associate Plus	[Redacted]	Active	20-Oct-2019	KS004	Active	Rave CRA
[Redacted]	Associate Plus	[Redacted]	Active	07-Mar-2020	KS004	Active	Rave CRA
[Redacted]	Associate Plus	[Redacted]	Active	07-May-2020	KS004	Active	Rave CRA
[Redacted]	Associate Plus	[Redacted]	Active	20-May-2020	KS004	Active	Rave CRA

- Export query output to Excel

Add Person |  |  | 

More RUMS Tips

- Find someone's CTEP ID using the CTEP ID Search

Person Roster Browser | Org Roster Browser | **CTEP ID Search** | Tracking

Jenny Hopkins

1 records found.

CTEP ID Search

#	First Name	Last Name	CTEP ID	Status	Expiration date	City	State	Zip Code
1	Jenny	Hopkins	892232		05 Oct 2020	Rockville	MD	20850

Note: The rows shown in red text indicate...

City/State/Zip help to confirm

Query on full or partial first and/or last name

- Use the RUMS Tracking tab to view and respond to roster owner queries

Person Roster Browser | Org Roster Browser | CTEP ID Search | **Tracking**

Status Filter: **Queried** Apply Filter Help Topics

#	Request ID	Request Date	Operation	Roster	Site	Site Name	CTEP ID	Name	Registration Type	Request Status	Action
1	892232	08-Aug-2019	Add Investigator	SWOG					Investigator	QUERIED	[Approve] [Deny] [Cancel]
2	892222	08-Aug-2019	Add Investigator	SWOG					Investigator	QUERIED	[Approve] [Deny] [Cancel]

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Viewing Regulatory Information

Use filters to focus your search

See what is needed to obtain approval

Site Registration | Protocol Requirements | Regulatory Submission

Site Number: [Redacted] Registration Status: Pending Protocol Status: All Protocol Statuses Help Topics

All IRB Types Protocol: [Redacted] Pick Go Disclaimer




#	Site	Protocol Number	LPO	Protocol Status	IRB Type	IRB Approval Expiration (Days)	CTSU Collecting IRB Continuing Review?	Member Of LPO or Registration PO	Site Registration Status	Missing Requirements (if applicable)
31	[Redacted]	S1400F	SWOG	Temporarily Closed to Accrual	CIRB	275	Yes	Y	Pending	Protocol is Temporarily Closed to Accrual
32	[Redacted]	S1501	SWOG	Active	CIRB	141	Yes	Y	Pending	Reqs not complied [Echo Lab Validation {due 05/31/2018}]
33	[Redacted]	S1600	SWOG	Active	CIRB	83	Yes	Y	Pending	Reqs not complied [Site Requirements Form {due 02/21/2019}]

Click on i button to view the site-protocol PI and the status of protocol requirements


Site Number [Redacted] Site Status : Pending Protocol : S1501
 Principal Investigator : [Redacted]
 Comment :
[Print](#)

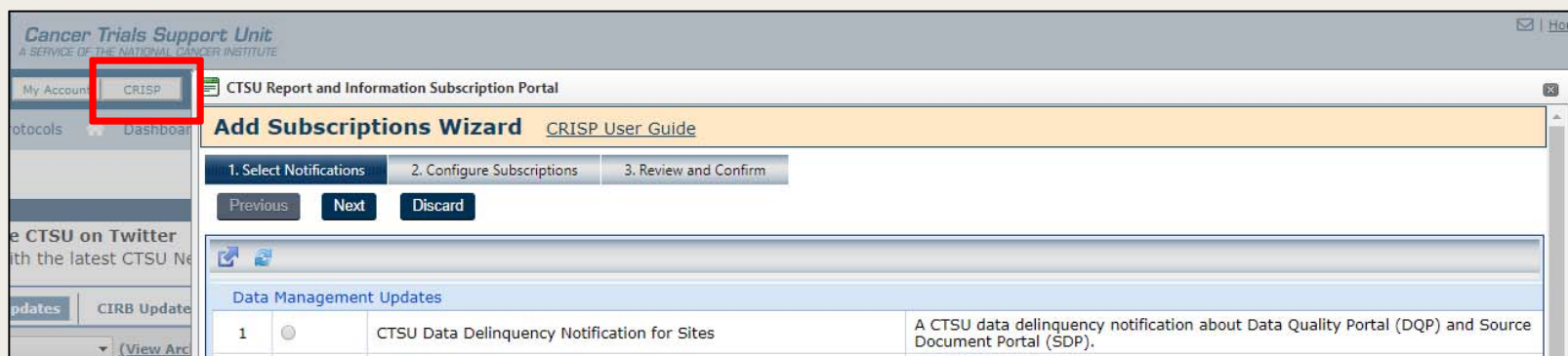
#	Code	Description	Required By Date	Required?	Complied?
1	IRB	IRB Approval	09/15/2017	✓	✓
2	SITE_QUALIFICATION	Echo Lab Validation	05/31/2018	✓	

Data Quality Portal Reminders and Tips

- DQP Access
 - Anybody rostered to a site can view the DQP; those with Rave-related roles can link directly into Rave from the DQP .
- DQP Reports
 - Aging Report Summaries
 - Delinquencies/Queries by Form
 - Rave Delinquencies/Queries
 - DQP Summary Table (*Rave Home*)
 - DQP Timeliness Reports (*Quarterly; Static*)
- Exporting DQP reports
 - Reports can be exported when the More Commands  icon or the Excel icon  is displayed.

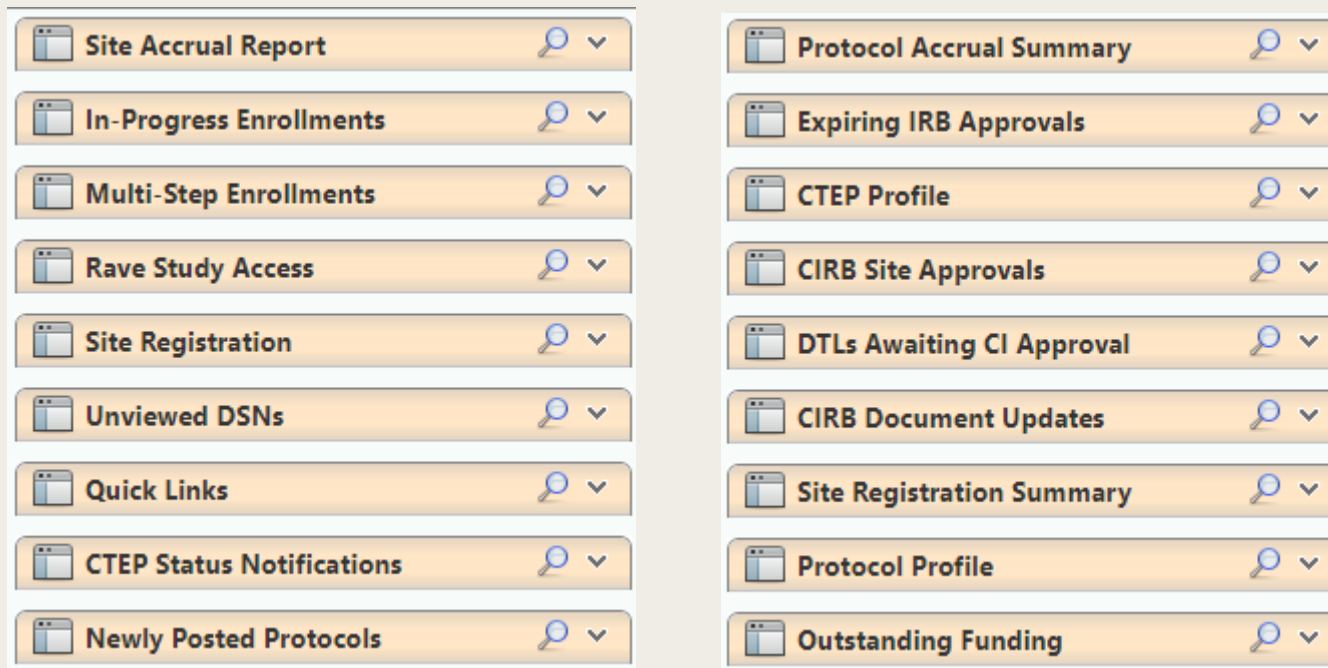
More DQP Reminders and Tips

- Remember that the DQP refreshes nightly.
- Drill down to the form/field level in Rave to find delinquent forms and outstanding queries that you can't see at the site, patient, or folder level.
- DQP User Guide
 - The DQP Site User Guide provides assistance for using the DQP and is accessible via the Help icon .
- Use CRISP to subscribe to bi-weekly notifications from the DQP (and SDP).



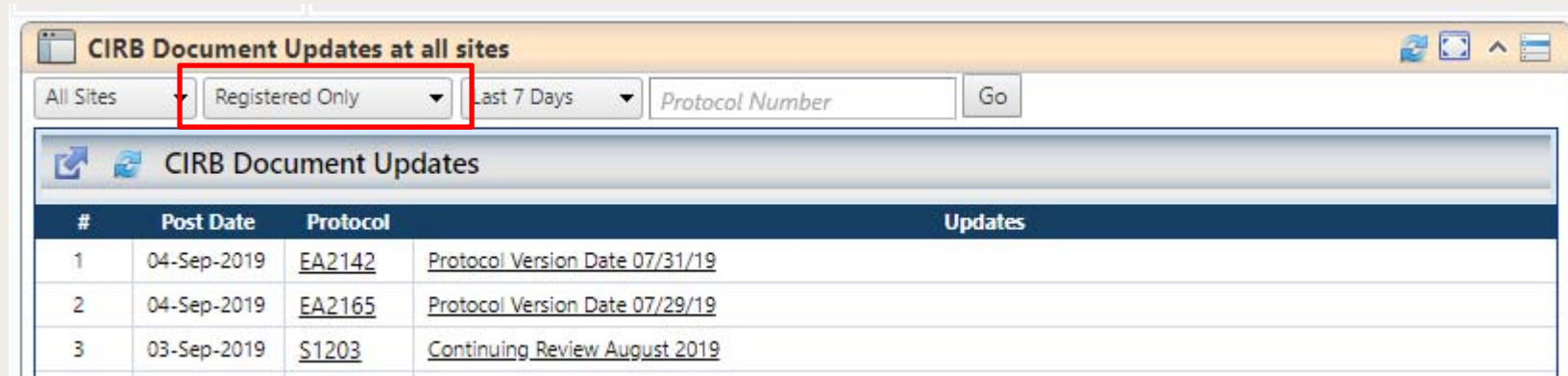
Dashboard Reminders and Tips

- The CTSU Dashboard contains all available data specific to each person, their associated sites, and protocols of interest. The Dashboard can be customized to suit your needs and preferences.
- Available portlets:



Dashboard, Cont.

- Many portlets contain information you can find elsewhere, but the dashboard allows you to see them in one place, *with your preferred filters in place*.
 - For example, you can view data only for the protocols your sites are registered for:



#	Post Date	Protocol	Updates
1	04-Sep-2019	EA2142	Protocol Version Date 07/31/19
2	04-Sep-2019	EA2165	Protocol Version Date 07/29/19
3	03-Sep-2019	S1203	Continuing Review August 2019

Which Studies Use Which Applications?

- In the Dashboard (Protocol Profile Portlet)

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

All Sites Video Tutorial Dashboard Management Info Profile: Protocol

Protocol Profile

Search Protocol: Active Go

1 150

#	Protocol Number	Status	Status Date	APCD	PCD	CIRB	OPEN	RAVE	TRIAD	TSDV	DQP	CM	DTL	CTEPAERS	EPRO
1	NRG-LU005	Active	28-May-2019	28-Dec-2026		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
2	S1800A	Active	17-May-2019	01-Feb-2023		✓	✓	✓	✓	✓	✓	✗	✓	✓	✗
3	S1803	Active	27-Jun-2019	01-Feb-2029		✓	✓	✓	✗	✓	✓	✗	✗	✓	✗
4	A031102	Active	01-Jul-2015	01-Jun-2024	16-Jan-2018	✓	✓	✓	✗	✓	✓	✗	✗	✗	✗
5	EA6134	Active	11-Apr-2016	02-Oct-2022		✓	✓	✓	✗	✓	✓	✗	✗	✗	✗
6	NSABP-B-51	Active	22-Aug-2013	31-Jul-2020		✓	✓	✓	✓	✗	✓	✗	✗	✗	✗
7	EAY131	Active	31-May-2016	30-Jun-2022		✓	✓	✓	✓	✓	✓	✗	✗	✗	✗
8	NRG-CC003	Active	09-Jan-2019	31-Jan-2022		✓	✓	✓	✓	✓	✓	✗	✗	✗	✗
9	E4512	Active	18-Aug-2014	01-May-2022		✓	✓	✓	✗	✓	✓	✗	✗	✗	✗
10	EA3161	Active	20-Jun-2019	01-Jan-2027		✓	✓	✓	✓	✓	✓	✗	✗	✓	✗

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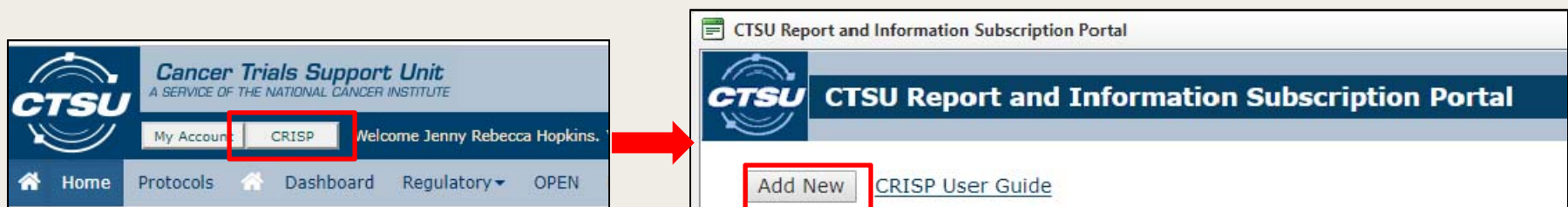
- In an individual protocol page

Supported By:

CIRB	OPEN	RAVE	IROC/TRIAD	TSDV	DQP	CM	DTL	CTEP-AERS/INTEG	ePRO
✓	✓	✓	✗	✓	✓	✗	✗	✓	✗

CRISP Notifications

- The CTSU Report and Information Subscription Portal (CRISP) allows staff to manage automated subscription e-mail notifications in a central location.
- Some automated emails are distributed to certain individuals based on their roster roles (e.g., Primary Contacts) or other activities (e.g., the individual who uploaded something in the SDP that was then rejected), but these and other notifications can also be subscribed to via CRISP.

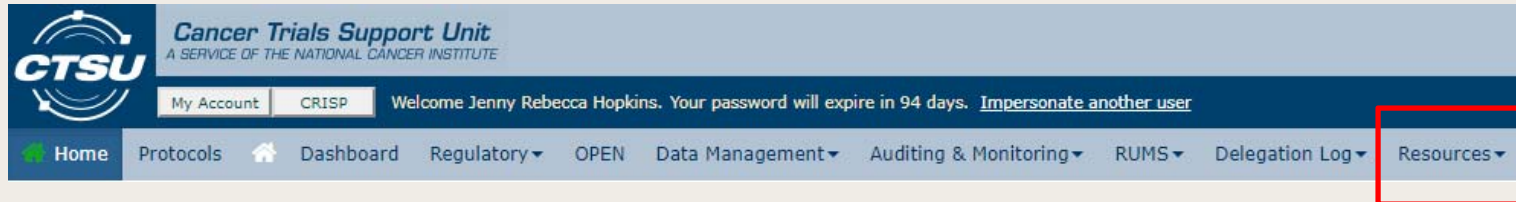


Available CRISP Notifications

Add Subscriptions Wizard CRISP User Guide			
1. Select Notifications 2. Configure Subscriptions 3. Review and Confirm			
<input type="button" value="Previous"/> <input type="button" value="Next"/> <input type="button" value="Discard"/>			
Data Management Updates			
1	<input type="radio"/>	CTSU Data Delinquency Notification for Sites	A CTSU data delinquency notification about Data Quality Portal (DQP) and Source Document Portal (SDP).
2	<input type="radio"/>	CTSU Source Document Portal Notification - Documents Rejected By the Lead Protocol Organization For Site	A CTSU Source Document Portal notification about rejected documents.
3	<input type="radio"/>	CTSU Adverse Event Reconciliation Notification : NCI Expedited Adverse Event Report is Recommended	A CTSU Data Management AE Reconciliation Notification about AE Missing Tickets.
Enrollment Updates			
1	<input type="radio"/>	Summary of Multi-step Enrollments at all Sites	Provides a summary of multi-step enrollments at your selected sites
2	<input type="radio"/>	Accrual Updates for Selected Protocols at your Site	Lists accrual updates for selected protocols at your site.
3	<input type="radio"/>	Step change for multi-step enrollments on selected protocols	Step change for multi-step enrollments on selected protocols
Person Roster Updates			
1	<input type="radio"/>	Summary of Changes to the Selected Person Rosters	Lists all roster additions/withdrawals including person role changes made to the selected roster during your specified time range
Protocol Updates			
1	<input type="radio"/>	New Protocols in Your Area of Interest	Lists all upcoming studies in your selected area of interest or disease category
2	<input type="radio"/>	Addition of New Protocol Versions (Summary)	Notification of Additional New Protocol Versions
Regulatory Updates			
1	<input type="radio"/>	IRB Approval Expiring in 30 Days	Lists all IRB approvals due to expire within 30-days
2	<input type="radio"/>	Site Registration Status Changes	Provides a summary of Site Registration Status Changes

More notifications are in development!

General Resources



- Resources area of the website
 - CTSU Operations Information is especially useful for those new to the CTSU
 - We are working to develop orientation/overview materials
- Remember the help content for individual pages and applications!
- CTSU Help Desk
 - CTSUContact@Westat.com
 - 1-888-823-5923



Questions?

The CTSU has a table at the ORP Open Forum this afternoon, where you can ask about this content or anything else.