



# Alliance NCTN Transition Update

Clinical Research Professionals Committee Meeting – May 8, 2014

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Trini Ajazi, Chief Administrative Officer

Denise Brennan, Chief Financial Officer

Marcia Kelly, Membership and Administrative Manager

Michael Kelly, Director, Protocol Operations

# Agenda

- *Personnel Updates*
- *National Clinical Trials Network (NCTN) Update\**
  - *NCTN Participation*
  - *Rostering issues*
  - *Payment model and mechanism*
  - *Training Update*
  - *Questions and answers (Q&A) session*

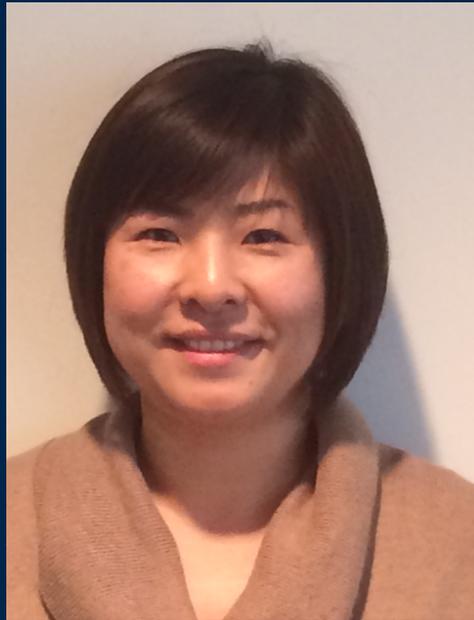
*\*Many slides provided by CTSU*

# Office of the Group Chair: New Personnel

Meetings and Operations Coordinator –  
Alison Lewandowski



# Central Protocol Operations Program Personnel Update



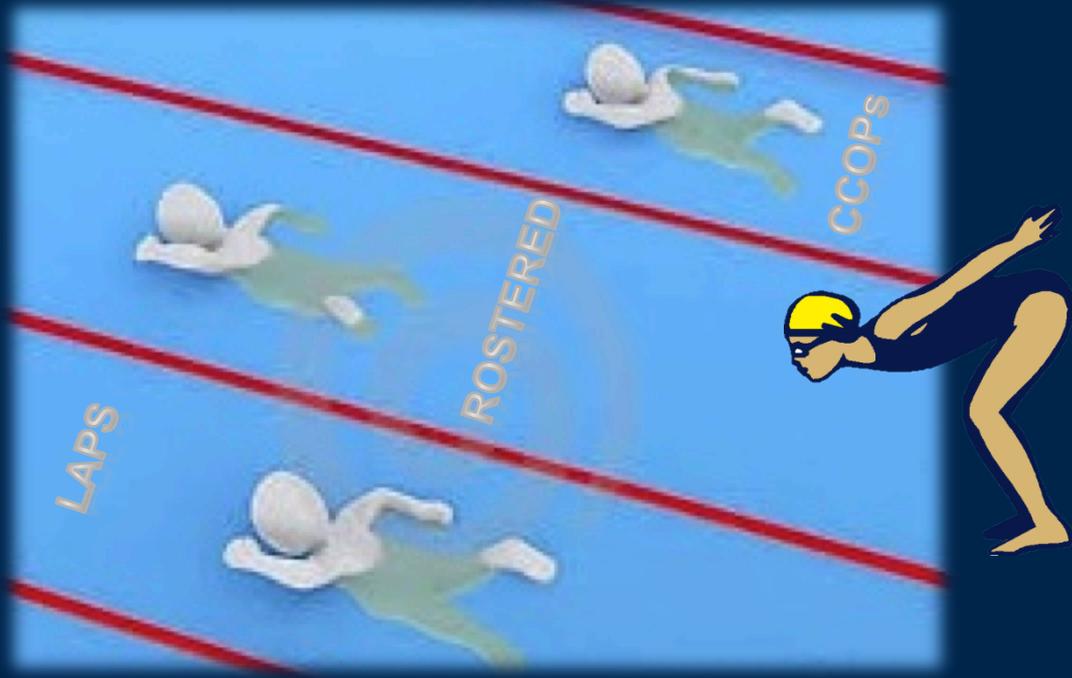
**Yujia Wen, MD, PhD**

Director of Translational Research  
March 2014

- Director of Translational Research Operations ~ 03/2014
- Post Doctorate in Clinical Pharmacology and Pharmacogenomics at the University of Chicago
- Molecular cancer biomarker development and oncology pharmacogenetics/genomics
- Supports both CPOP and Translational Research Program

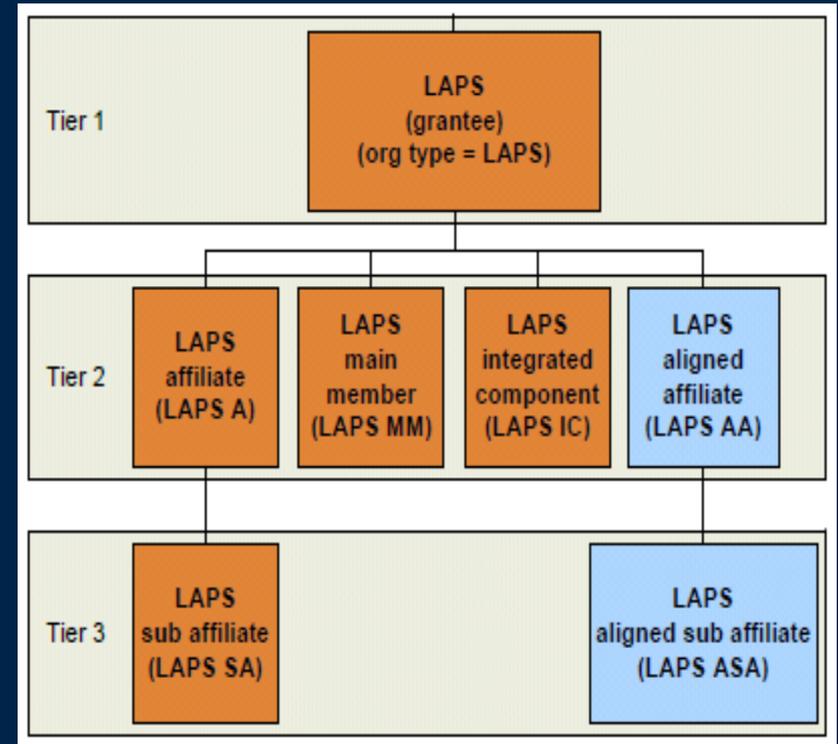
# NCTN Swim Lane Rule

- Adult Group sites must function under a LAPS grant, a CCOP grant, or under the NCTN Group grants (Rostered) and can only participate under one of these mechanisms (swim lane rules).

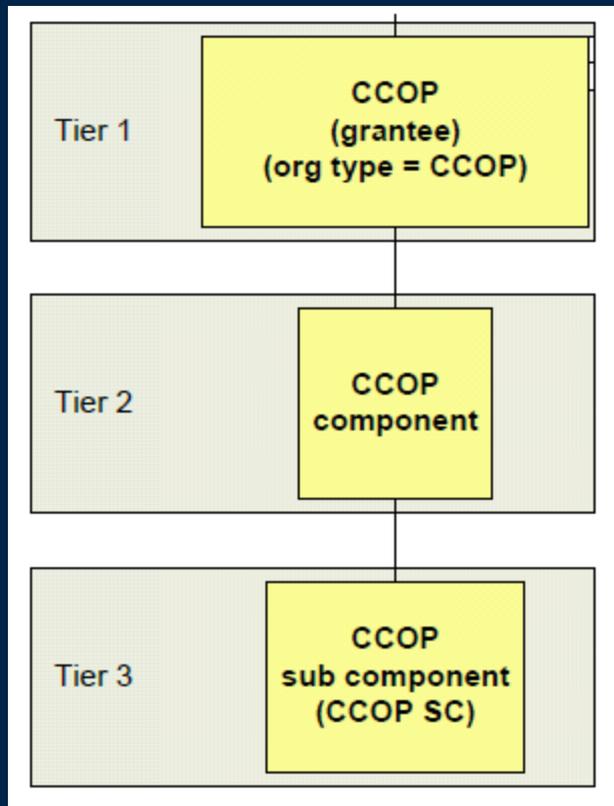


# Participation Rules for LAPS

- Tier 1 sites are administrative and cannot accrue subjects.
- Tier 2 and Tier 3 sites are enrolling sites and are eligible for audit.
- LAPS may be on multiple Group rosters and Groups must claim all sites within the LAPS grant.
- Enrollments for LAPS sites will be paid for by the LAPS grant.
- Enrollments for the LAPS aligned affiliates and LAPS aligned sub affiliates will be paid by the credited Network Group(s).



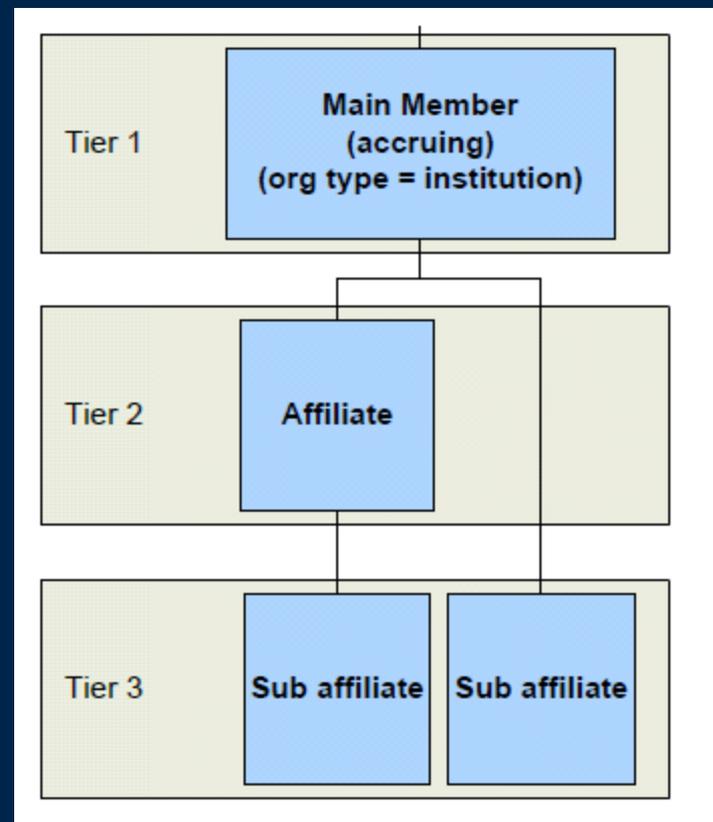
# Participation Rules for CCOPS/MB-CCOPS



- Tier 1 sites are administrative and cannot accrue subjects but may be eligible for audit.
- Tier 2 and Tier 3 sites are enrolling sites and are eligible for audit.
- CCOPs may be on multiple Group rosters and Groups must claim all sites within the CCOPs grant.
- CCOP enrollments will be paid for by the CCOP grant.

# Participation Rules for Adult Network Groups

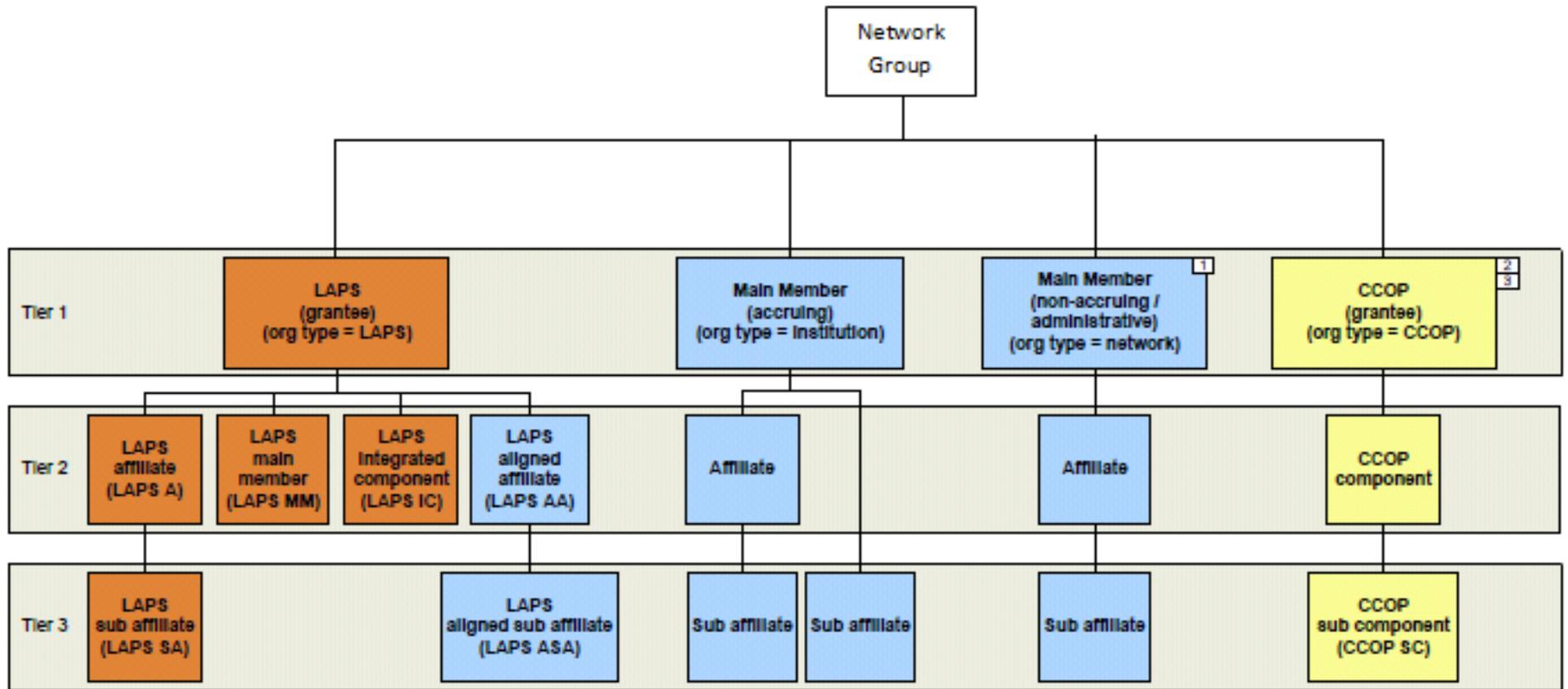
- Tier 1 Main Members, all Tier 2 Affiliates and Tier 3 Sub affiliate sites are enrolling sites.
- All enrolling sites will be eligible for audit.
- Sites can be on multiple NCTN rosters.
- Main Member/Affiliate sites can participate in multiple tiers across groups, but can only be claimed once by a group (e.g. Main Member for Group A, but Affiliate for Group B).



# Crediting Rules

- US sites may credit any participating Network Group to which the site and credited investigator are affiliated and participating on the protocol.
- Canadian sites must credit the NCTN Group that holds the CTA.
- International sites must credit the Lead Protocol Organization (LPO) if they are a member of the LPO.
- International sites that are not members of the LPO must receive approval from their credited group and consistently credit the same group for the protocol.

# Network Group Structure



- LAPS Package
- Rostered
- CCOP Package

1	Pre-approval for Main Member (non-accruing / administrative) code required from CTEP
2	Attribute for MB CCOP provided by DCP and viewable in RSS
3	Attribute for PEDS ONLY provided by DCP and viewable in RSS

# What Sites Should be Rostered?

Per Clinical Trials Monitoring Branch:

any site where patients are **consented** must be  
on the membership roster

# Maintaining Person Rosters

# Adding/Deleting Persons for CCOPs

## Community Clinical Oncology Program Cedar Rapids Oncology Project CCOP

Home > My Program

Profiles Components Persons Roles **Rosters** History

Rosters tab describes rostering to NCTN groups and Cancer Center Research Bases.

Show All Statuses:

### Cedar Rapids Oncology Project CCOP (CROP)

Research Base	Status	Possible Actions	Status Date	Status By
<a href="#">ALLIANCE</a>	Active	<a href="#">withdraw</a>	02-11-2014 - 2:05 PM	CCOPSYS Administrator
<a href="#">COG</a>		<a href="#">add</a>		
<a href="#">ECOG-ACRIN</a>		<a href="#">add</a>		
<a href="#">MDA</a>		<a href="#">add</a>		
<a href="#">NRG</a>		<a href="#">add</a>		
<a href="#">URCC (NY167)</a>		<a href="#">add</a>		
<a href="#">HLMCC (SCUSF)</a>		<a href="#">add</a>		
<a href="#">SWOG</a>		<a href="#">add</a>		
<a href="#">CCWF (WAKE)</a>	Active	<a href="#">withdraw</a>	02-11-2014 - 12:51 PM	CCOPSYS Administrator

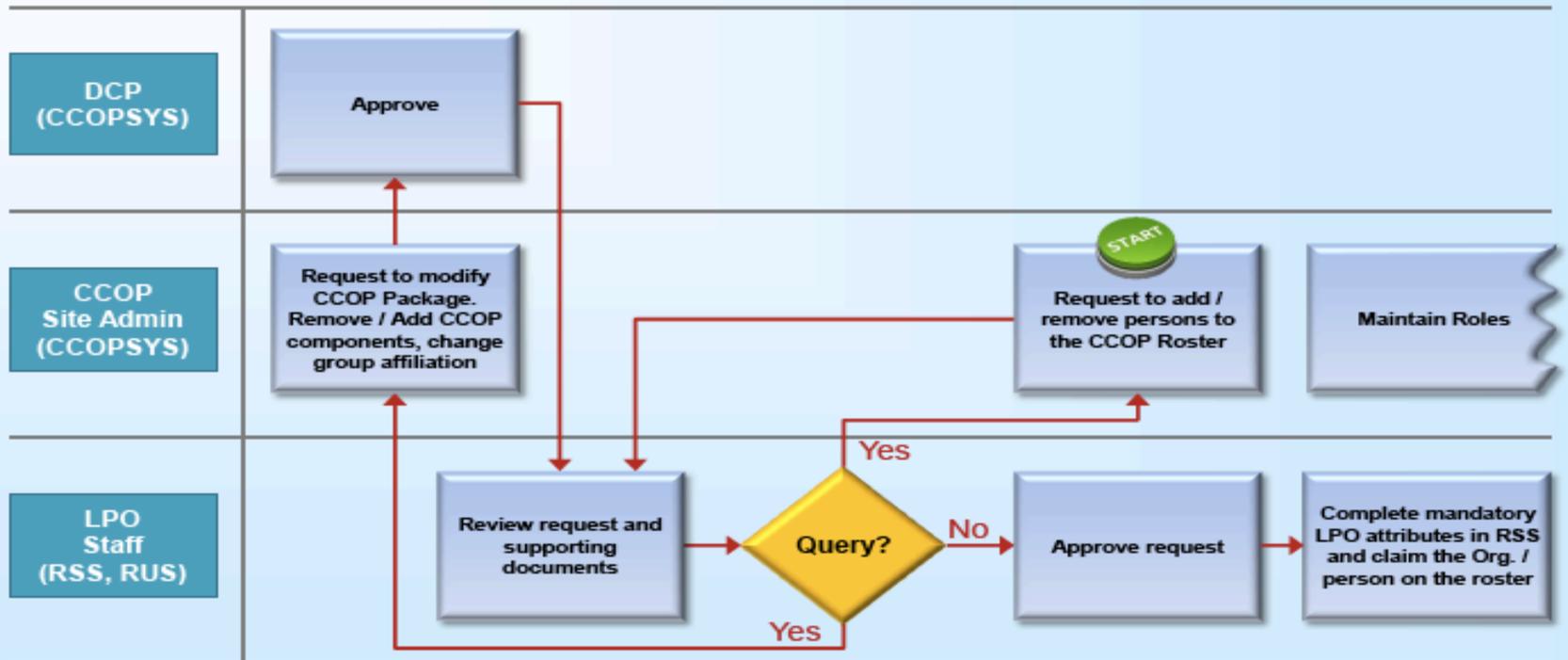
 [Request Addition to a Research Base Roster.](#)

 [Request Withdrawal from a Research Base Roster.](#)

Can request that a package be added or withdrawn from a roster.

# Workflow for CCOP Sites (Post Transition)

From March 2014 onwards



# Adding/Deleting persons from LAPS and Non-CCOPs



Member Login

Search    
Advanced Search

[home](#) [about](#) [clinical trials](#) [membership](#) [patient advocacy](#) [news](#) [foundation](#)

[Home](#) > [Individual Participation](#)



## INDIVIDUAL PARTICIPATION

The Alliance membership structure is composed of institutional membership with investigators and non-investigators on the member institution's roster. All persons being added to the Alliance roster must have an NCI ID (investigators) or a CTEP ID (non-investigators). Information on how to obtain an NCI ID or CTEP ID can be found at: [https://www.ctsu.org/public/RegProced\\_ir-ar.aspx](https://www.ctsu.org/public/RegProced_ir-ar.aspx)

### Adding or deleting persons from the Alliance roster for non-CCOP members

**Investigators and staff:** To add or delete a person from the Alliance roster the Lead CRP should sign and submit a completed [roster update form](#) to [roster@AllianceNCTN.org](mailto:roster@AllianceNCTN.org). For all new persons, please also submit a copy of their Human Subject Protection Training Certificate.

**Principal Investigators:** To change an institution's Principal Investigator (PI) a letter of notification of the change signed by both the outgoing and incoming PI must be addressed to the Group Chair and submitted to the Membership Manager at [membership@AllianceNCTN.org](mailto:membership@AllianceNCTN.org). Please include within the letter the effective date and if the outgoing PI will continue membership as an investigator or will need to be withdrawn. In addition to the letter of notification, submit a roster form, [Alliance COI Form](#), CV or NIH Biosketch, and a copy of the Human Subject Protection Training Certificate for the incoming PI.

**Co-Principal Investigators, Lead Clinical Research Professional (CRP), and Secondary Lead Clinical Research Professionals:** To change Co-PIs, Lead CRP, and Secondary Lead CRPs submit a roster form to [membership@AllianceNCTN.org](mailto:membership@AllianceNCTN.org).

# Updating Person Roles

**CTSUS** Cancer Trials Support Unit  
A SERVICE OF THE NATIONAL CANCER INSTITUTE

Home | Contact | Feedback | Public Site | Log Out  
Version: 6.0.0

My Account: Welcome Marcia Kelly. Your password will expire in 27 days.

Home Protocols **Regulatory** OPEN RAVE Clinical Data Education & Resources Collaboration

RSS Browser Site Roles Site Registration Notification Protocol Req CTEP ID Search

Select Roster to View: CTSU Roster Update Form Roles & Access Print Training Video Help Site Roles Slide Set

Show All Persons All Sites All Roles All

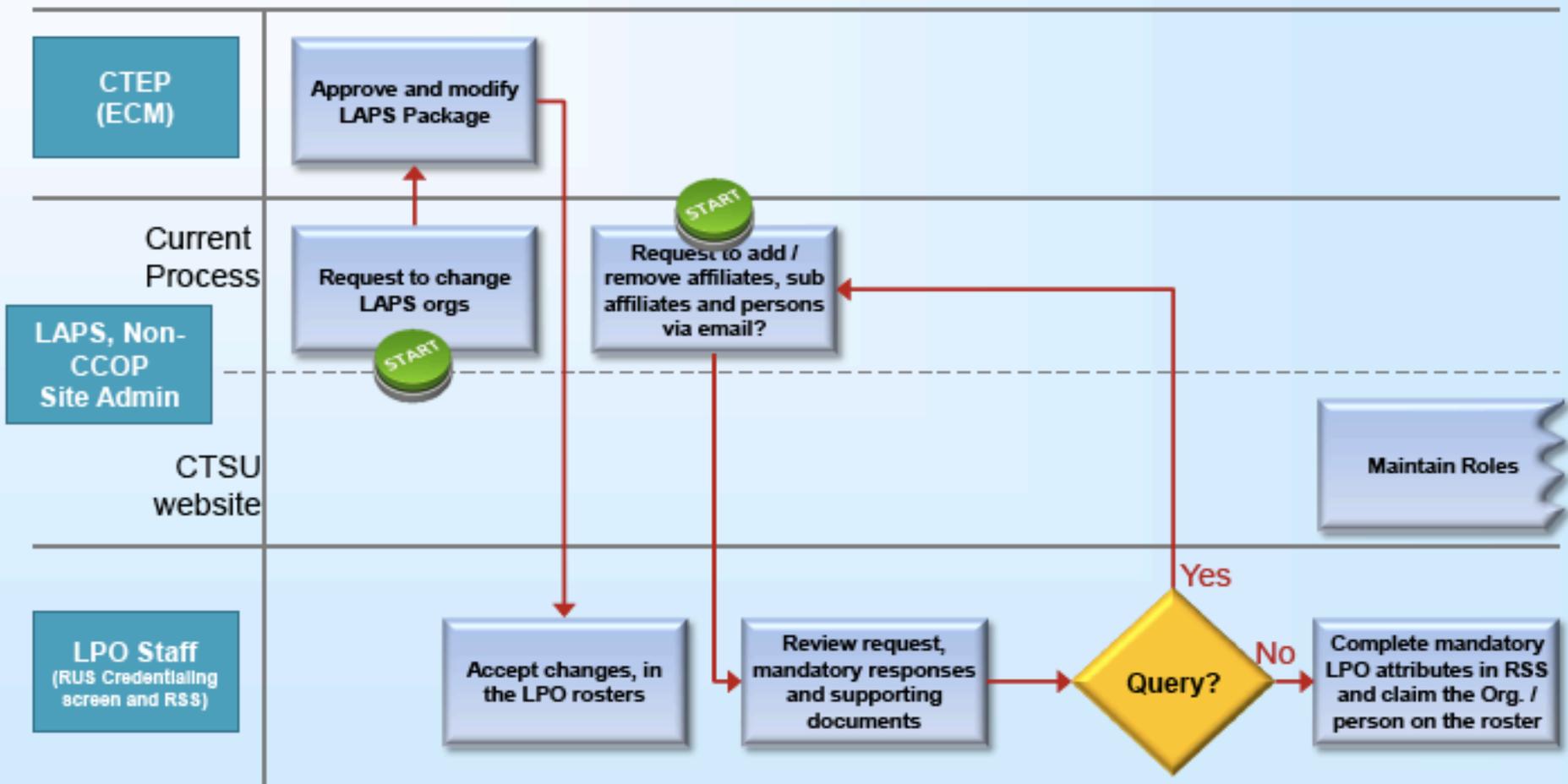
I/A	CTEP ID	Name	CTEP Reg. Dt.	Action	Site	Role	Protocol/Role	Effective Date
					ALLIANCE			
A	524573	Abbott, Rhonda	07/25/2014		MN026	Panel Member	CSC	05/26/2011
					NCCTG			
A	534007	Agar, Nathalie YR	02/13/2015		CALGB			
					MA036	Other		07/12/2013
					ALLIANCE	List Serve Member		02/28/2014
				Membership Coordinator			02/28/2014	
				Group Administrator			02/28/2014	
				Panel Member		Stakeholders Working Group	02/28/2014	
				Panel Member		OPEN	02/28/2014	
				Panel Member		CODE	02/28/2014	
				Panel Member		CSC	02/28/2014	
				Regulatory Associate			02/28/2014	
A	504071	Ajazi, Trinidad	10/25/2014			Membership Coordinator		07/23/2010
						List Serve Member		01/31/2011

**RSS Browser**

- Kelly, Marcia (505322)
- ADM400: Alliance Chicago Office (ALLIANCE)
- ALLIANCE: Alliance for Clinical Trials in Oncology
- CALGB: Cancer and Leukemia Group B (CTSUS)
- Site Roles
- Search
- Regulatory and Roster Forms and Resources
- RSS Announcements
  - There are currently no announcements.
- Contact Information

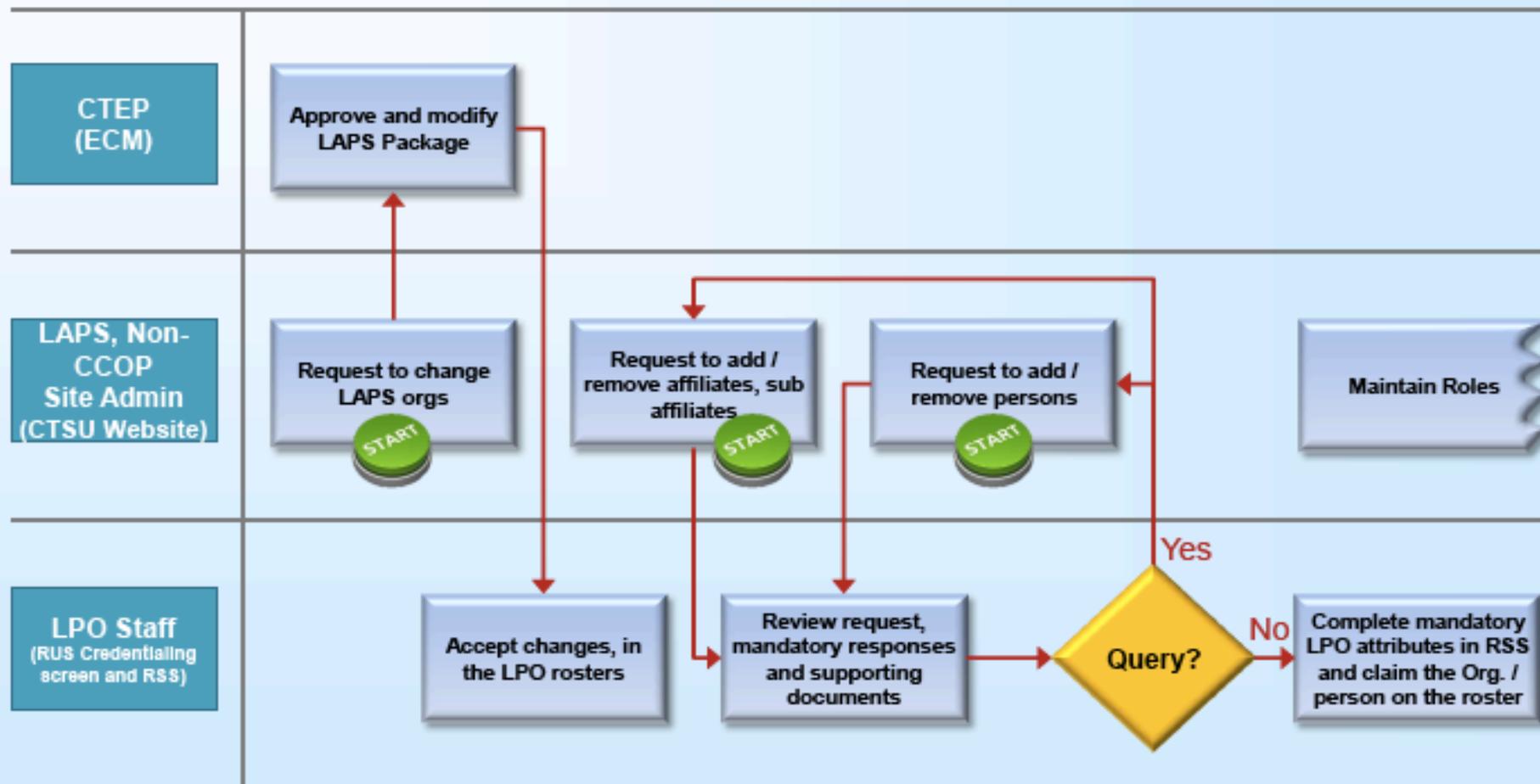
# Workflow for LAPS/Non-CCOP Sites (Post Transition)

From Mar to July 2014



# Workflow for LAPS/Non-CCOP Sites (Post Transition)

From July 2014 onwards



# ROLES

System	Role for all Rosters
Rave	Rave CRA, Read Only, Site Investigator
OPEN	Registrar
TRIAD	Site User



# Payments

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# Federal payment categories

- Funding for trial activities will fall under one of the following categories:
  - Screening for Intervention
  - Basic Intervention
  - Advanced Imaging
  - Biospecimen Collection
  - Special (complex or rare disease trials)
  - Quality of Life
  - Non-NCI/DCTD Funding (e.g., Industry)

# Federal payment types

- Funding pages updated on CTSU website for each NCTN protocol
- Funding levels are approved by CTEP prior to protocol activation

## CTSU Funding Information (other sources of funding may be available, please review the Funding Documents)

4 records

#	Funding Source	Funding Type	Funding Type #	Specify	Mandatory	\$ Value	CCOP Credit	Funding Status
1	DCTD	Base Intervention			Mandatory	\$2,250.00		ACTIVE
2	DCTD	Biospecimen	1	Bio-specimen - Tumor (Block)	Optional	\$100.00	0	ACTIVE
3	DCTD	Biospecimen	2	Bio-specimen - Plasma	Optional	\$300.00	0	ACTIVE
4	DCTD	Biospecimen	3	Bio-specimen - Peripheral Blood	Optional	\$50.00	0	ACTIVE

# OPEN and payment triggers

- For 'mandatory' funding types such as 'basic intervention' or 'screening,' completion of the patient enrollment in OPEN is considered the triggering event for payment eligibility
- For imaging and biospecimen payments, site staff are required to enter data via OPEN at the time the site becomes eligible for payment
- Funding screen will only be visible when there is optional or conditional funding for a study

# Optional and conditional funding

- Optional Funding Type – A test or evaluation that is offered to the patient but is not required for the patient to participate on the study
- Conditional Funding Type - A test or evaluation that is required per the protocol for patient participation on a study but is dependent upon other parameters, such as patient eligibility

# OPEN Funding Screen

Home Slot Reservation Enroll **History** Reports RSS Form Setup Admin Help

Browse | Summary | Prerequisite | Demography | Checklist | **Funding** ?

Selected Tracking # **169991** [Details](#) [Summary](#)

Protocol	PID	Initials (LFM)	Step	Arm	Site	Investigator	Status	Status Date
E1208	12197	GR-	1	X	CA011	El-Khoueiry, Anthony	REGISTERED	01/30/2014

- Protocol Funding:
  - Enter the completion date for each funding type when completed
  - Completion dates cannot be changed after 7 calendar days of initial entry

Funding Type	Funding Type #	Specify	Date Completed (MM/DD/YYYY)	
Biospecimen	1	Bio-specimen - Tumor (Block)	02/18/2014	<input type="text"/> Clear
Biospecimen	2	Bio-specimen - Plasma	<input type="text"/>	<input type="text"/> Clear
Biospecimen	3	Bio-specimen - Peripheral Blood	<input type="text"/>	<input type="text"/> Clear

A completion date is required for reimbursement

Funding Type, Funding Type # and Specify will be pre-filled based on funding available for the study.

# Foundation payments

- Available to all sites and dispersed from Group credited
  - Phase II complexity for concepts approved by CTEP prior to 8/31/2012
  - Supplemental funds for NCI trials
  - Pass through payments from other Groups



# Alliance Online Training

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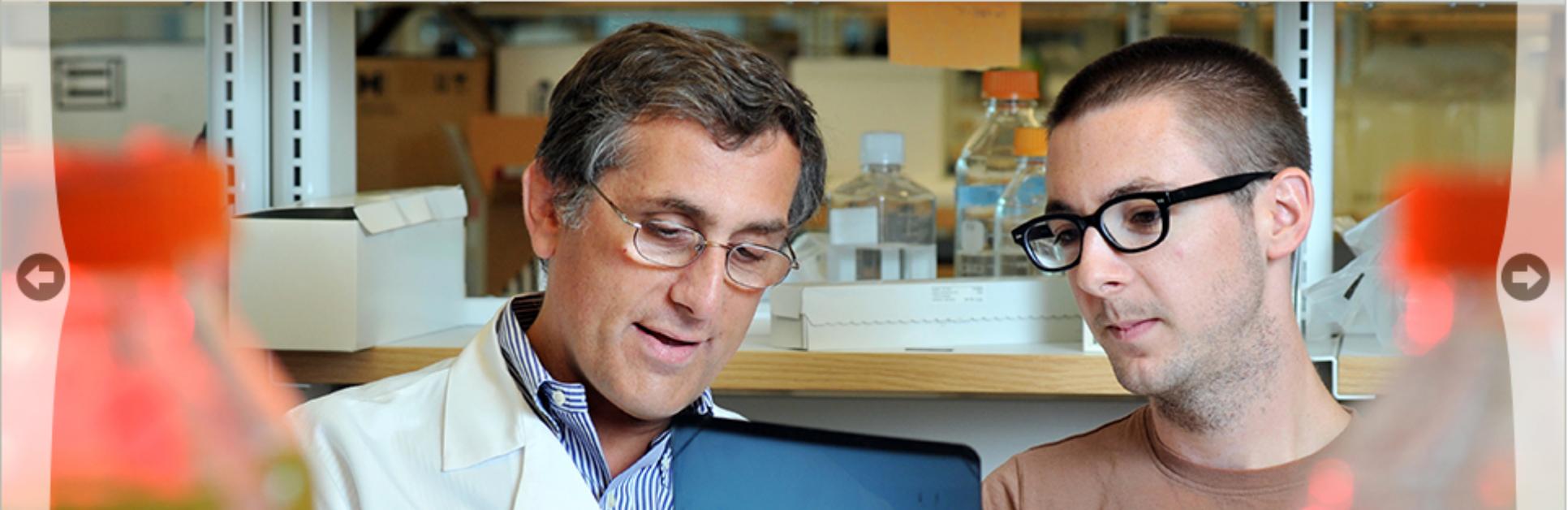


Access to Online Training is through the ALLIANCE member website. You will need to know your CTEP-IAM username and password.

[Member Login](#)

  
[Advanced Search](#)

- [home](#)
- [about](#)
- [clinical trials](#)
- [membership](#)
- [patient advocacy](#)
- [news](#)
- [foundation](#)



# Online Training

Home > [Online Training](#)

Online Training is located under the Education & Training menu.

## ALLIANCE ONLINE TRAINING

Alliance Online Training is now available. Download the [user guide](#) and [get started](#). If needed, download [Adobe Flash Player](#). Current training topics are listed below.

[Online Training](#)

[Resources](#)

### For Site Staff:

- [Audit Preparation](#)
- [Resources for Clinical Research Professionals](#)
- [Geriatric Assessment](#)
- [Informed Consent](#)
- [Institutional Review Boards](#)

### For Alliance Study Chairs:

- [Concept Development](#)
- [Protocol Development](#)

Click on “get started” to enter the course catalog.

Home Groups Learning resources

**Catalog**

- Search form
- My entries
- My courses
- My supervised courses
- Courses
- CP learning content
- SCORM learning content
- Wikis

**CATALOG ROOT**

Learning resources

- Auditors: Auditor Training
- Site Staff: Audit Preparation**
- Site Staff: Geriatric
- Site Staff: Inform
- Site Staff: Institut

**Site Staff: Audit Preparation**  
For site staff  
How to prepare for an Alliance audit  
Revised February 2014

From the catalog, hover over any learning resource name to see details.

Click on a resource name to continue.

# Catalog

- **For Site Staff:**
  - Resources for Clinical Research Professionals
  - Informed Consent
  - Institutional Review Boards
  - Audit Preparation
  - Geriatric Assessment
  - CALGB 140503 Presentation

# Catalog continued

- **For Alliance Study Chairs:**
  - Concept Development
  - Protocol Development
  - Translational Research Program – Concept and Protocol Development
  - Study Conduct
  - Publications Overview

# Catalog continued

- **For Alliance Auditors: Auditor Training**
- **Upcoming Training Topic: Alliance Member Orientation**
- **Questions? Send an e-mail to [training@allianceNCTN.org](mailto:training@allianceNCTN.org)**



# Questions & Answers

Q&A from Town Hall web conference posted on  
Alliance website

