SWOG Oncology Research Professionals

Jeri & Noboru Oishi Symposium

Welcome & Announcements	Connie Szczepanek
Regulatory 101 Panel Discussion	Anthony Hicks, Melina Rodriguez, Jennifer Haynes & Shawn England
Understanding the PMB	Matt Boron
Know Your IRBs Panel Discussion	Joyce Nancarrow Tull, Jacquie Steenbakker, Laura Covington, Ashley Tydon, Mary Gay Lapasaran, Melina Rodriquez & Shawn England
SWOG Perspectives & Common Challenges Panel Discussion	Cara Laubach, Elaine Armstrong, Laura Gonzales, Maggie Spillers, Amy Koffarnus, Caitlin Hutchinson, Rachel Kitchen & Jessica Franzke
Past Accomplishments & Hope for the Future	Joyce Nancarrow Tull

SWOG
Oncology Research Professionals (ORP) Committee
Announcements

Fall 2022

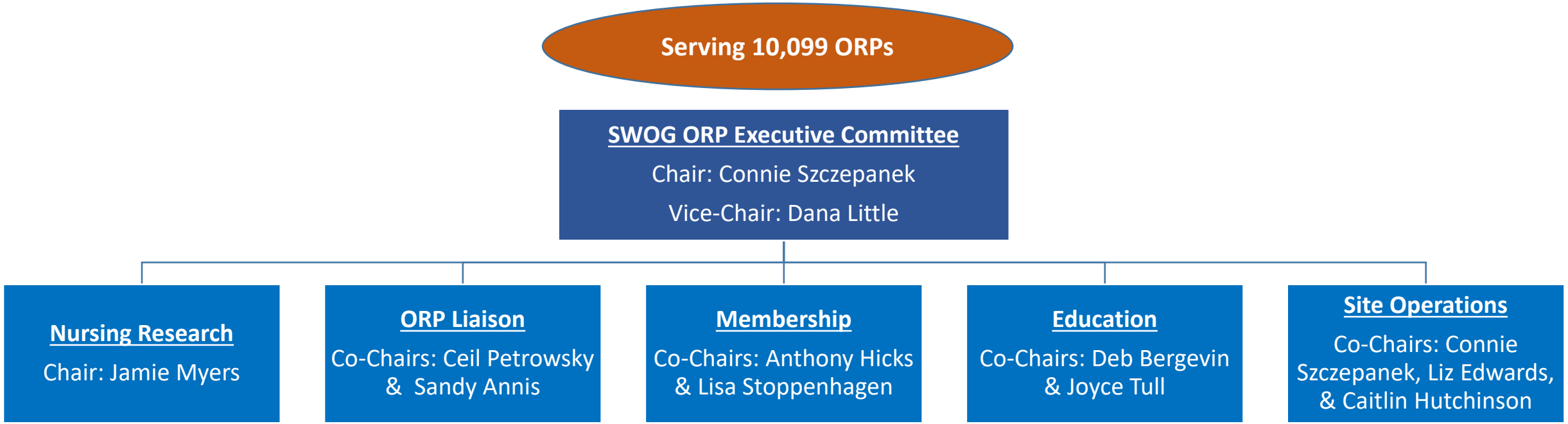
Logistics Details

- Please keep your phone on mute to help with sound quality.
- Questions can be submitted all throughout the meeting via the CHAT icon. We will present them to the speakers during the meeting.
- The presentations will be posted on the SWOG website within a few weeks.
- Although there are no formal CE credits for this meeting, you may print a copy of the agenda to reflect your attendance (e.g.: for use with SOCRA or ACRP).

YOU are The ORP Committee!

"SWOG holds a fundamental conviction that the **O**ncology **R**esearch **P**rofessionals (ORP) play a crucial role in the successful development, implementation, and analysis of any SWOG clinical trial."

The SWOG Oncology Research Professionals (ORP) Committee & Sub-Committees



SWOG Cancer Research Network's Mission

- To significantly improve lives through cancer clinical trials and translational research.

ORP Committee Mission

- To support SWOG activities through promotion of integrity and excellence in clinical research through education, guidance, & collaborative contributions.

Acknowledgements

ORP Executive Committee Members	
Sandy Annis	Jamie Myers
Deb Bergevin	Joyce Nancarrow-Tull
Annette Betley	Ceil Petrowsky
Anthony Hicks	Lisa Stoppenhagen
Caitlin Hutchinson	Connie Szczepanek
Dana Little	

YOU are The ORP Committee!

To get more deeply involved, see the SWOG Website:

Member Resources / Membership / Committee Membership

https://www.swog.org/member-resources/membership/committee-membership

Key Involvement Opportunities

- Disease Specific Liaisons
- Liaisons at Large
- Education Team

The Role of an ORP Liaison

An ORP Liaison is a member of both the ORP Liaison Committee and a specific SWOG committee.

- **Reviews protocols in development** and provides feedback from a site and role perspective.
- Provides feedback to the SWOG Disease Committee after the study is activated addressing any **site implementation concerns**.
- Participates in **the development of tools** to assist research sites with study selection, implementation and compliance.
- Maintains **active lines of communication** with SWOG Protocol coordinators and committees.
- Reviews of **ORP Manual chapters**.
- **Mentors and supports** development of new liaison

Open Liaison Positions

Disease Committee	Position
Breast	Research Nurse
Symptom Control	Research Nurse
Early Therapeutics	Research Nurse and CRA
Gastrointestinal	Research Nurse
Leukemia	Research Nurse
Lymphoma	Research Nurse
Myeloma	CRA

An *At Large Liaison Member* is:

- A CRA or RN that is a member of the ORP Liaison Committee and not a specific SWOG committee.
- A member of the ORP Liaison Committee may attend ORP Liaison Committee conference calls, participate in committee projects and receive mentoring from an experienced Liaison while awaiting an opening on a disease committee.

Co- Chair ORP Liaison Committee Ceil Petrowsky RN MSN OCN CCRC cpetrow@luc.edu
Co- Chair ORP Liaison Committee Alexandra Annis CRA aannis2@kumc.edu

SWOG ORP Resources

Home / Member Resources / CRA Workbench

Find ORP Resources on the CRA Workbench

Your resource headquarters for SWOG clinical trial patient management.

Latest CRA Newsletter

Join the CRA Mailing list

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

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

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

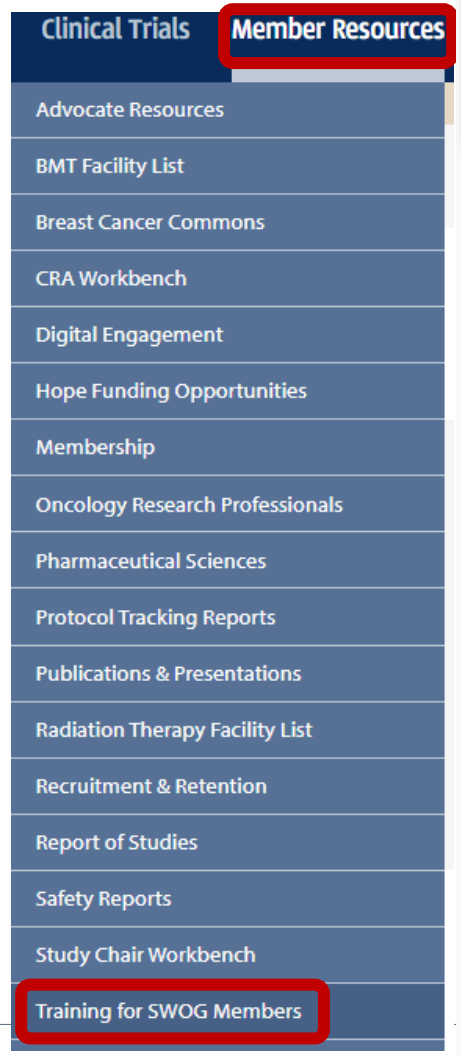
- SWOG Clinical Trials Training Course (CTTC)
- Your First Group Meeting
- Every CRA Should Know...

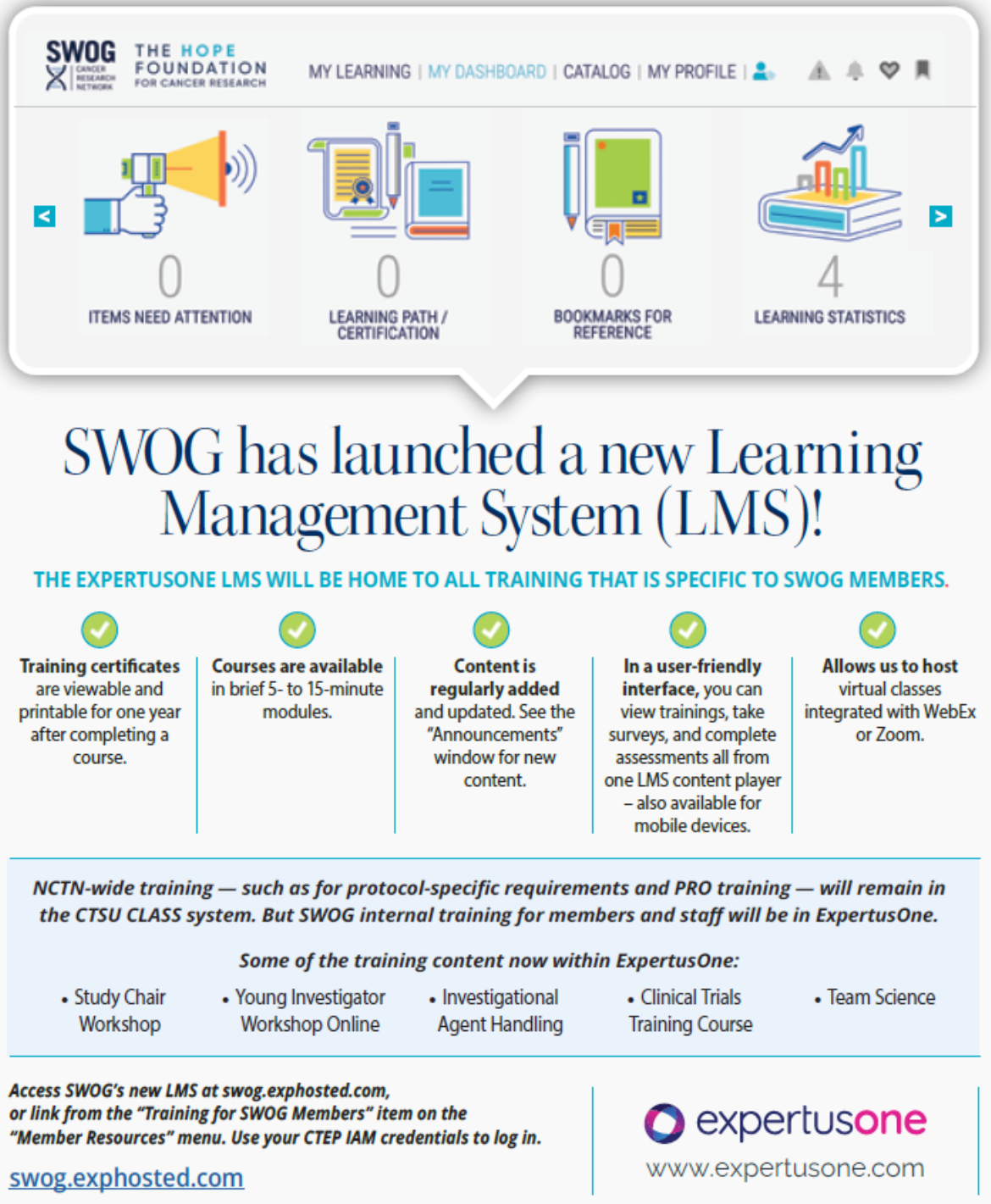
Study Reports

- 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

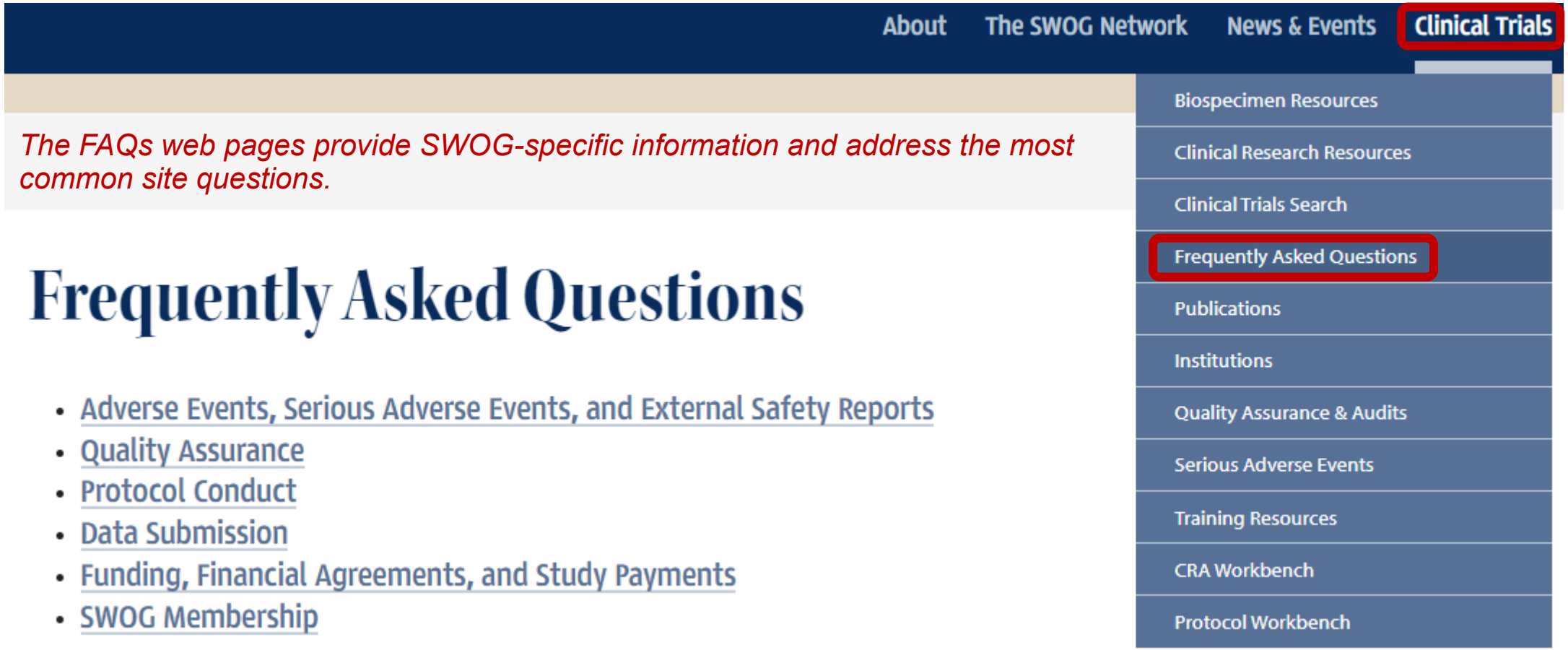
New SWOG Learning Management System (LMS)

- Direct link to the LMS is located on the SWOG Member-side of the website under the “Member Resources” menu,
  - Also accessible to SWOG Members via direct url: https://swog.exposted.com.
  - Login with CTEP IAM credentials required to access.
- Online Clinical Trials Training Course, plus
  - Brief (5-15 minutes) modular course additions ongoing.
- All new 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.





Frequently Asked Questions *Webpages* *(Launched Spring 2022)*



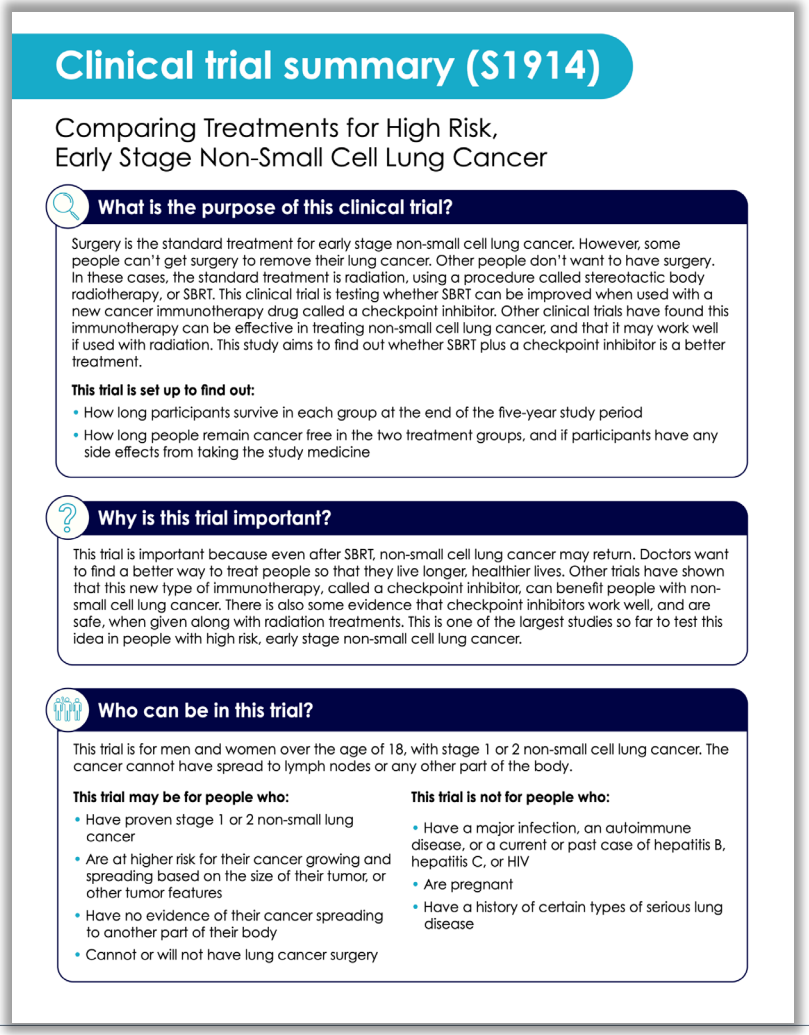
Clinical Research Resources *Webpages (Launched Fall 2021)*

- Resources for Oncology Research Professionals
  - ❖ SWOG Data Submission Guidance, Tips, and Tricks
- Regulatory and Ethical Research Conduct References, such as the NIH Department of Bioethics Videocasts of Past Lectures
- Human Subjects Research Protection Training
- Continuing Education and Training Programs

Patient-Friendly Summaries and Social Media Toolkits

- Linked from SWOG.org/clinical-trials and CTSU.org pages for newly activated trials.
- Summary questions selected by a team of patient advocates & health education experts to give patients key info to help them decide whether they want to learn more about a study.

S1914



Clinical trial summary (S1914)

Comparing Treatments for High Risk, Early Stage Non-Small Cell Lung Cancer

What is the purpose of this clinical trial?

Surgery is the standard treatment for early stage non-small cell lung cancer. However, some people can't get surgery to remove their lung cancer. Other people don't want to have surgery. In these cases, the standard treatment is radiation, using a procedure called stereotactic body radiotherapy, or SBRT. This clinical trial is testing whether SBRT can be improved when used with a new cancer immunotherapy drug called a checkpoint inhibitor. Other clinical trials have found this immunotherapy can be effective in treating non-small cell lung cancer, and that it may work well if used with radiation. This study aims to find out whether SBRT plus a checkpoint inhibitor is a better treatment.

This trial is set up to find out:

- How long participants survive in each group at the end of the five-year study period
- How long people remain cancer free in the two treatment groups, and if participants have any side effects from taking the study medicine

Why is this trial important?

This trial is important because even after SBRT, non-small cell lung cancer may return. Doctors want to find a better way to treat people so that they live longer, healthier lives. Other trials have shown that this new type of immunotherapy, called a checkpoint inhibitor, can benefit people with non-small cell lung cancer. There is also some evidence that checkpoint inhibitors work well, and are safe, when given along with radiation treatments. This is one of the largest studies so far to test this idea in people with high risk, early stage non-small cell lung cancer.

Who can be in this trial?

This trial is for men and women over the age of 18, with stage 1 or 2 non-small cell lung cancer. The cancer cannot have spread to lymph nodes or any other part of the body.

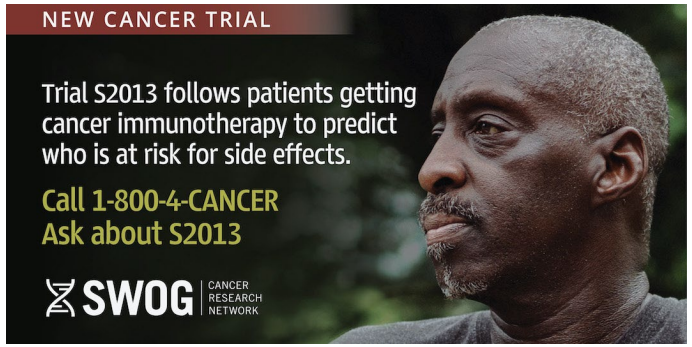
This trial may be for people who:

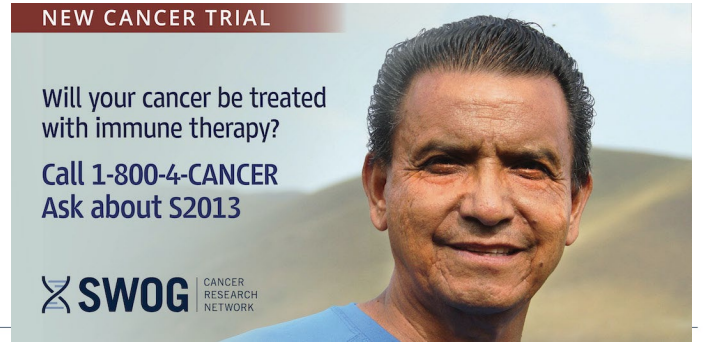
- Have proven stage 1 or 2 non-small lung cancer
- Are at higher risk for their cancer growing and spreading based on the size of their tumor, or other tumor features
- Have no evidence of their cancer spreading to another part of their body
- Cannot or will not have lung cancer surgery

This trial is not for people who:

- Have a major infection, an autoimmune disease, or a current or past case of hepatitis B, hepatitis C, or HIV
- Are pregnant
- Have a history of certain types of serious lung disease

S2013



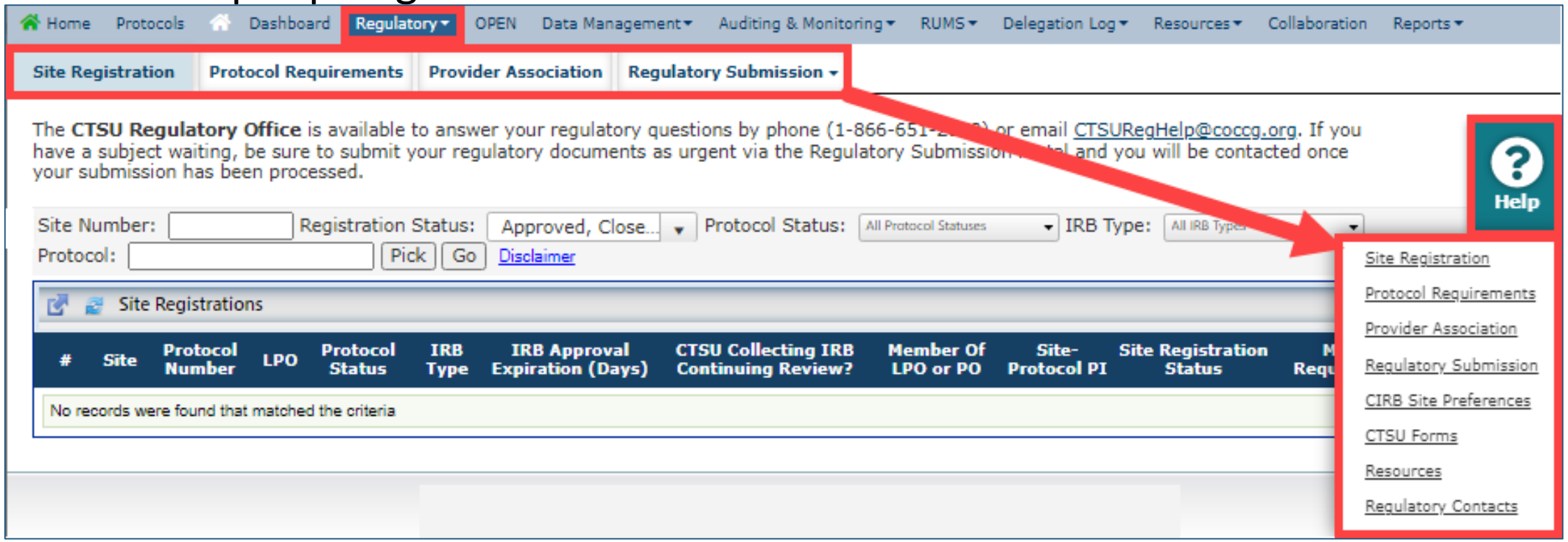


CTSU Resources

For New Site Staff

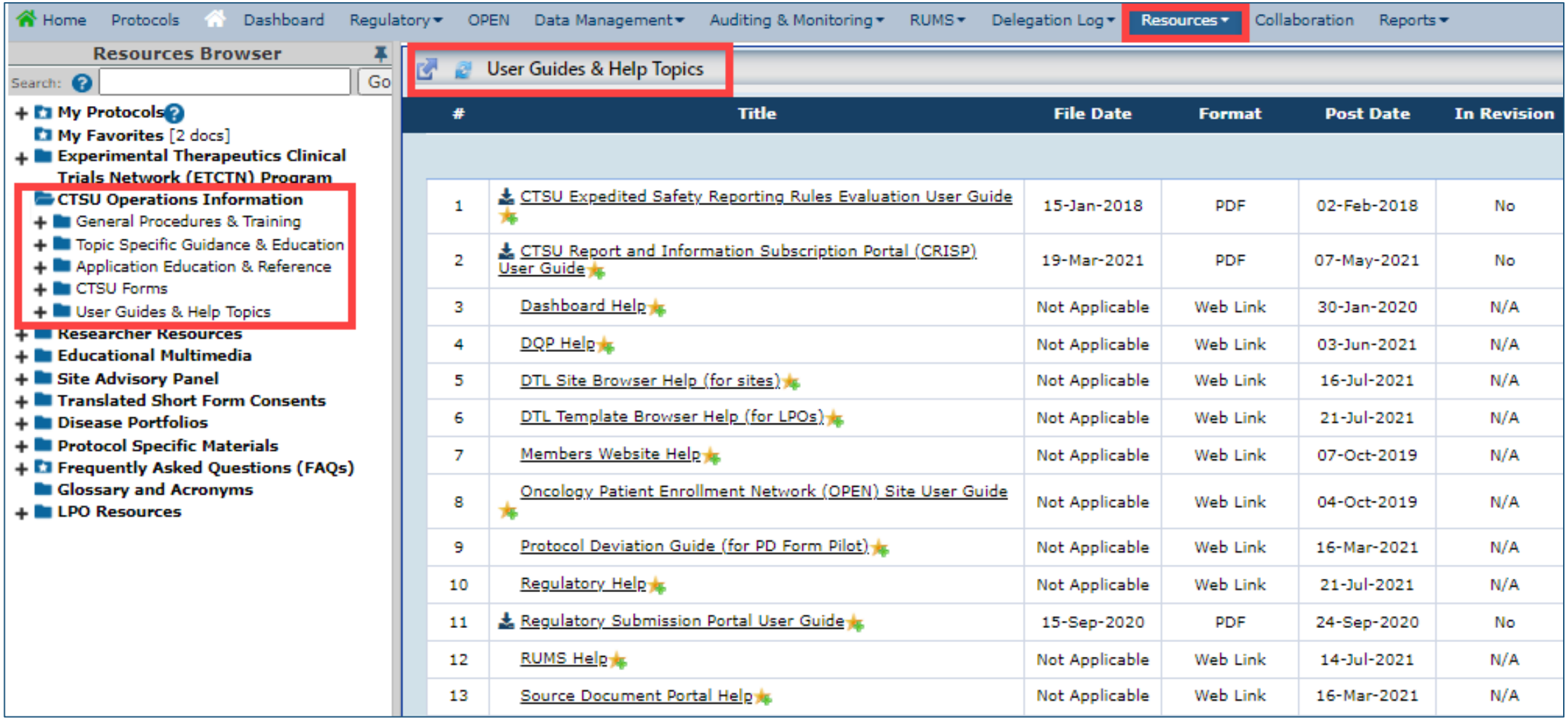
Help Topics

- 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



Resources: Central Location for Help Topics

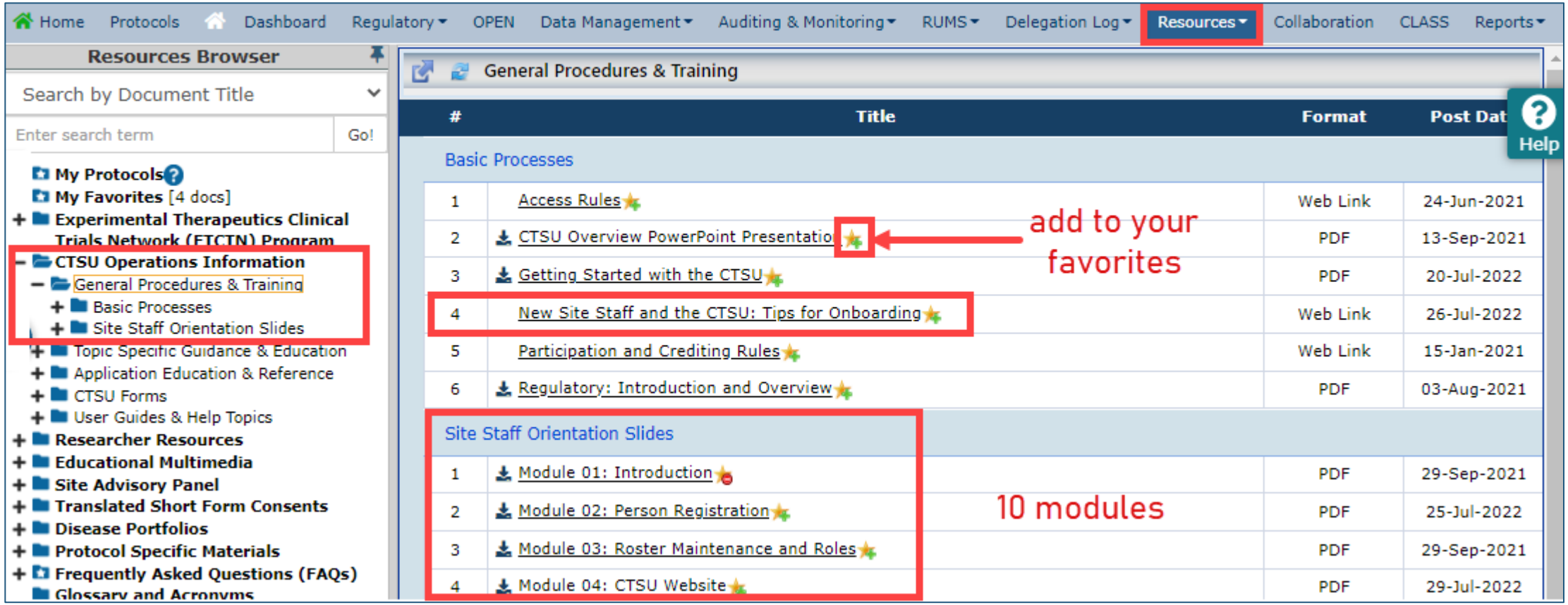
- **All** help topics appear in the Resources section → CTSU Operations Information → User Guides & Help Topics



#	Title	File Date	Format	Post Date	In Revision
1	CTSU Expedited Safety Reporting Rules Evaluation User Guide	15-Jan-2018	PDF	02-Feb-2018	No
2	CTSU Report and Information Subscription Portal (CRISP) User Guide	19-Mar-2021	PDF	07-May-2021	No
3	Dashboard Help	Not Applicable	Web Link	30-Jan-2020	N/A
4	DQP Help	Not Applicable	Web Link	03-Jun-2021	N/A
5	DTL Site Browser Help (for sites)	Not Applicable	Web Link	16-Jul-2021	N/A
6	DTL Template Browser Help (for LPOs)	Not Applicable	Web Link	21-Jul-2021	N/A
7	Members Website Help	Not Applicable	Web Link	07-Oct-2019	N/A
8	Oncology Patient Enrollment Network (OPEN) Site User Guide	Not Applicable	Web Link	04-Oct-2019	N/A
9	Protocol Deviation Guide (for PD Form Pilot)	Not Applicable	Web Link	16-Mar-2021	N/A
10	Regulatory Help	Not Applicable	Web Link	21-Jul-2021	N/A
11	Regulatory Submission Portal User Guide	15-Sep-2020	PDF	24-Sep-2020	No
12	RUMS Help	Not Applicable	Web Link	14-Jul-2021	N/A
13	Source Document Portal Help	Not Applicable	Web Link	16-Mar-2021	N/A

New Site Staff 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



Funding Opportunities

CRA and Nurse Travel Support Program

- Provides traveler funding for group meeting attendance
- Offered through SWOG's public charity, **The Hope Foundation for Cancer Research**
- Watch for notices regarding Applications for the SWOG Spring Meeting visit: **tinyurl.com/CRA-NURSE**

Reminders

Spring 2023 SWOG Group Meeting

- May 10-13, 2023
- Hyatt Regency San Francisco
- San Francisco, California


take what
you need
love
hope
passion
courage


MERCY
LN
GRACE

Regulatory 101 Panel Discussion

Facilitator: Anthony Hicks, BS, CCRP
Operations Supervisor – CRCWM

Regulatory 101 Panelists

Introducing Our Panelists:

- Melina Rodriguez from Fred Hutchinson Cancer Center
- Jennifer Haynes from Margaret R. Pardee Memorial Hospital
- Shawn England from University of Kentucky, Markey Cancer Center
- Facilitator & Topic Consultant: Anthony Hicks from Spectrum Health Butterworth

Anthony Hicks, BS, CCRP
Operations Supervisor – CRCWM

Cancer Research Consortium of West Michigan
Committed to Community Cancer Research & Education

Institution Name: Spectrum Health Butterworth

SWOG Membership: NCORP – Cancer Research Consortium of West Michigan (CRCWM)

NCI CIRB: 3 Component sites

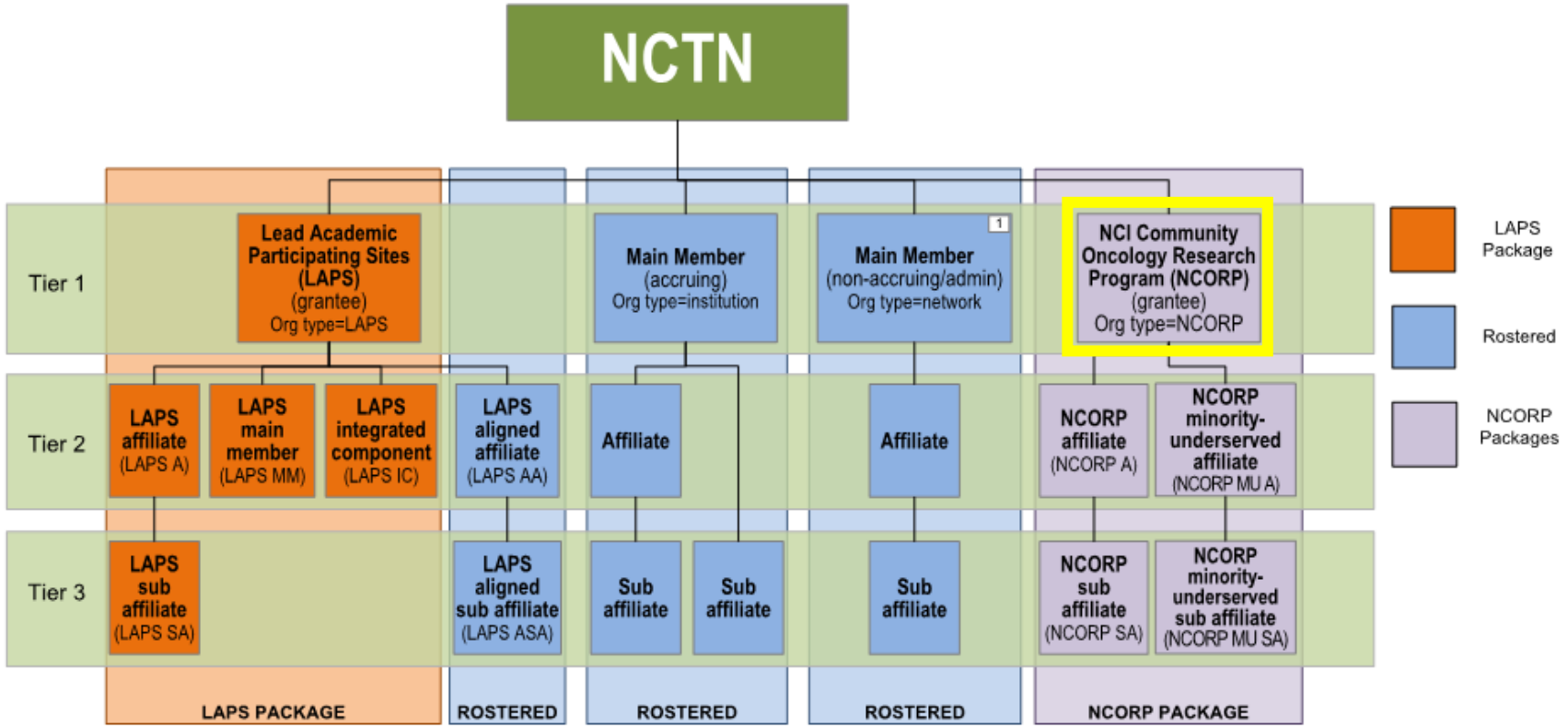
Number of affiliates: 13 affiliate sites

Number of active trials: 171 active clinical trials

Years Experience: 6 years of regulatory and cancer clinical research

Fun Fact: I love to spend my fall weekends musky fishing.

Where is Your Membership Swim Lane?



1. Pre-approved for Main Member (non-accruing / administrative code) required for CTEP.

Anthony Hicks, BS, CCRP
Operations Supervisor – CRCWM

How do you onboard and train new regulatory coordinators?

CRCWM onboarding of regulatory coordinators is quite robust and intricate. We utilize a regulatory manual as well as training and education SOPs/standalone processes that keep us organized. Overall, we like to tier our regulatory trainings over 3 to 4 phases over a 6 month-1 year timeline. (Or up to the research background/experiences of the person. Everyone is different.)

How does your organization and membership structure impact your onboarding process?

Our regulatory team is centrally located so we are all in the main office (virtually or in person), so that is advantageous.

Anthony Hicks, BS, CCRP
Operations Supervisor – CRCWM

When you onboard a new coordinator, what tools do you use to stay organized?

We utilize an orientation checklist to stay organized through the onboarding process. We also have regularly scheduled meetings to keep us on pace.

When you were onboarded, what was the most helpful tip you received?

I think the most helpful tip I received is that regulatory is a lot and to stay organized! It takes time to fully wrap your head around each and every regulatory process. When you reflect on that first year, it's crazy the amount of information you will learn especially if you don't come from a research background.

Anthony Hicks, BS, CCRP
Operations Supervisor – CRCWM

How do you collect credentials at your institution? (i.e., GCP, CVs, IATA and/or bloodborne pathogens, RUMS, RCR, NCORP sys, CAPs and/or CLIAs of local laboratories, etc.)

CRCWM is lucky to have an individual (Shout out to Nancy Adams) who collects and onboards/credentials all our research staff and physicians.

Does your institution have SOPs regarding credentialing?

Yes, we have multiple SOPs that outlines credentialing/training to be able to participate in research.

Anthony Hicks, BS, CCRP
Operations Supervisor – CRCWM

What tips and tools do you use to maintain credentials?

We utilize our shared drive as well as a Microsoft access database to maintain credentials for all our staff. We have credentialing checklists as well!

What systems do you have in place to prevent lapses in credentials?

Regarding RCR, our RCR coordinator receives reminders about RCR upcoming expirations (30- and 60-day reminders). We also keep track of medical licenses, GCP and HSP training, COI training, dangerous goods, and now ID me in Microsoft access.

Anthony Hicks, BS, CCRP
Operations Supervisor – CRCWM

How do you organize and maintain essential documents throughout the trial? (i.e., CTMS, eRegulatory, shared drive, paper)

We maintain all our essential documents through a shared drive, our website (CRCWM.org), and Credit, (our CTMS).

Do you have any tips or tools for the upkeep of amendments, submission deadlines, required documentation?

Our reg team utilizes and stays organized with an excel worksheet for each of our IRBs. (CIRB, local, and Advarra) For each of those IRBs, we utilize separate pages within excel file for study initiation, amendments, CRs and study completion. We utilize formulas within excel to make sure we consistently make our deadlines.

Anthony Hicks, BS, CCRP
Operations Supervisor – CRCWM

How do you ensure PI oversight of essential documents?

Our PI meets with our regulatory team weekly, and we review any important topics at that time. (We also communicate throughout the week depending on the need.) Our PI reviews all research base broadcasts, and we have a reoccurring monthly meeting where our PI goes over any amendments, action letters, CRs, study completions, local SAEs, and other admin updates.

Why do you think knowledge about basic regulatory requirements are important to everyone's individual role on the research team?

I think regulatory is the backbone of clinical research. Whether you are a nurse, CRA, or treating physician, an understanding of regulatory requirements is extremely important and keeps our consortium running and compliant.

Melina Rodriguez, BS, ACRP-CP
Regulatory Coordinator – Fred Hutch Cancer Center

FRED HUTCH / UNIVERSITY OF WASHINGTON / SEATTLE CHILDREN'S
CANCER CONSORTIUM

Institution Name: Fred Hutchinson Cancer Center (FHCC)

SWOG Membership: LAPS - FHCC

NCI CIRB: 1 signatory site

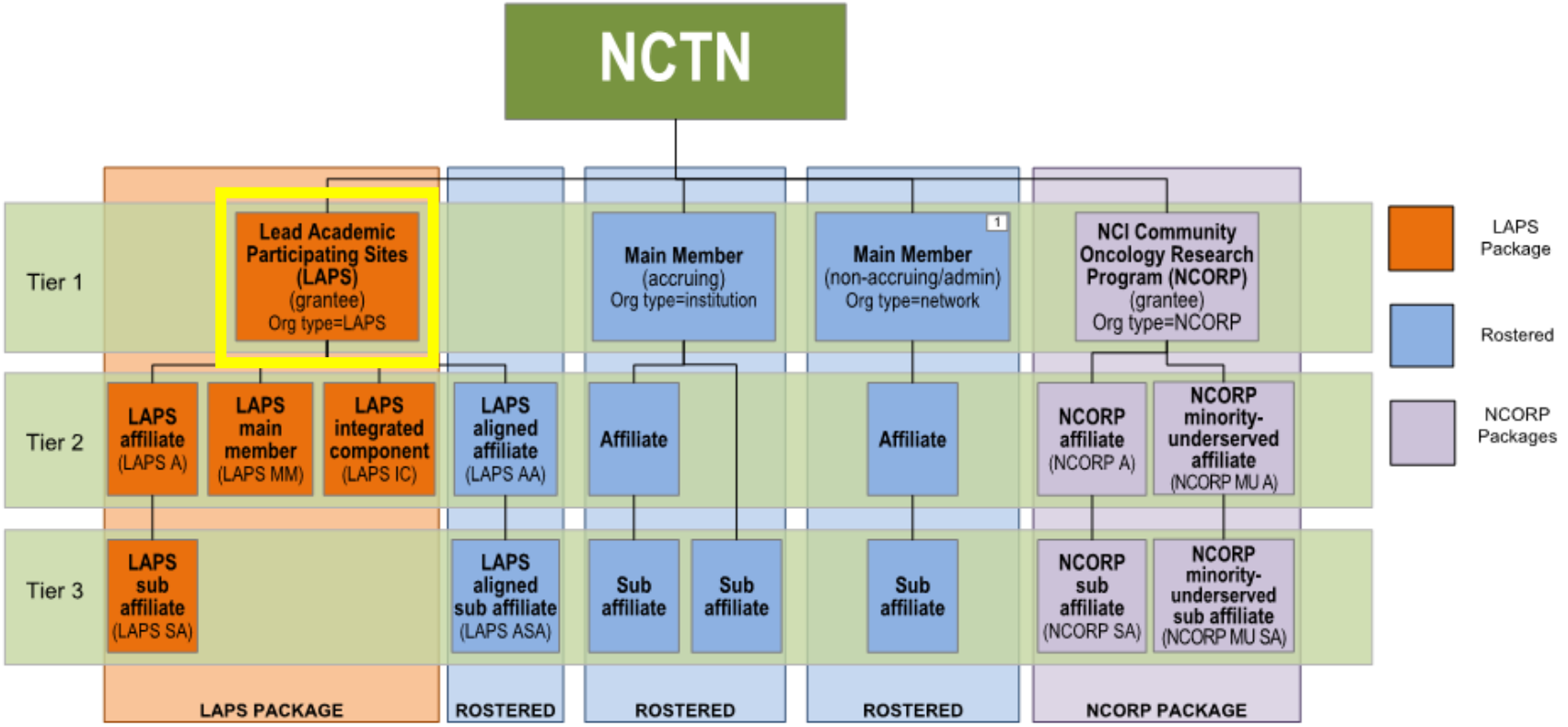
Number of affiliates: 24 affiliate sites

Number of active trials: 109 active clinical trials

Years Experience: 6 years in public health + oncology research, including 2 years spent in regulatory

Fun Fact: On weekends you can find me at concerts or embroidering; both are favorite pastimes!

Where is Your Membership Swim Lane?



1. Pre-approved for Main Member (non-accruing / administrative code) required for CTEP.

Melina Rodriguez, BS
Regulatory Coordinator – Fred Hutchinson Cancer Center

How do you onboard and train new regulatory coordinators?

- Shadowing, video training, LMS, CRS/CTMS webinar trainings, SOP review

How does your organization and membership structure impact your onboarding process?

- Group effort streamlines credentialing and onboarding
- Shared mailbox + Zendesk for tracking training requests and other credential items

Melina Rodriguez, BS
Regulatory Coordinator – Fred Hutchinson Cancer Center

When you onboard a new coordinator, what tools do you use to stay organized?

- Excel tracker checklist, Teams' channels for stand-up and training resources

When you were onboarded, what was the most helpful tip you received?

- Do not rely on recall; write it down!

Melina Rodriguez, BS
Regulatory Coordinator – Fred Hutchinson Cancer Center

How do you collect credentials at your institution? (i.e., GCP, CVs, IATA and/or bloodborne pathogens, RUMS, RCR, NCORP sys, CAPs and/or CLIAs of local laboratories, etc.)

- Florence eBinders is used as a repository for credentials (GCP, CV, HSP, med license) for faculty/staff
- Institutional credentials (CAPs, CLIAs) are housed on our internal Clinical Research Resources Website (SharePoint)

Does your institution have SOPs regarding credentialing?

- Yes

Melina Rodriguez, BS
Regulatory Coordinator – Fred Hutchinson Cancer Center

What tips and tools do you use to maintain credentials?

- Create shared mailbox to capture queries related to new staff, updated credentials
- Florence eBinders for maintaining essential documents
- CTMS OnCore for maintaining CTEP credentials

What systems do you have in place to prevent lapses in credentials?

- For RCR management, this is centralized in our NCTN program office to manage centrally; there is a dedicated institutional wide registration coordinator and back up registration coordinator to ensure these are done on time.
- Florence allows users to place an expiration date on the document to alert teams of upcoming expirations
- Credentials (CV, GCP, HSP) are stored in Florence, so lapses are rare but if they occur, they are handled by our central office team.

Melina Rodriguez, BS
Regulatory Coordinator – Fred Hutchinson Cancer Center

How do you organize and maintain essential documents throughout the trial? (i.e., CTMS, eRegulatory, shared drive, paper)

- CTMS, Florence eBinders, and shared drive

Do you have any tips or tools for the upkeep of amendments, submission deadlines, required documentation?

- Project management software and Florence
- Weekly meetings with team

Melina Rodriguez, BS
Regulatory Coordinator – Fred Hutchinson Cancer Center

How do you ensure PI oversight of essential documents?

- CTMS and Florence

Why do you think knowledge about basic regulatory requirements are important to everyone's individual role on the research team?

- Regulatory requirements can be likened to a game rulebook; Reg Coordinators act as referees.
  - ➢ By understanding the standards (rules) that govern clinical research (game), the study team can collectively take ownership of patient safety (fair play) and quality research (fair outcomes).

Jennifer Haynes, BSN, RN, OCN, CCRC
IRB Coordinator & Clinical Research Nurse

Institution Name: Margaret R. Pardee Memorial Hospital, Hendersonville, NC

SWOG Membership: NCORP – Southeast Clinical Oncology Research Consortium (SCOR)

NCI CIRB: 1 site

Number of affiliates: no affiliates

Number of active trials: 70 active clinical trials

Years Experience: 5 years of regulatory and cancer clinical research; 19 years oncology nursing

Fun Fact: I have a very good memory for song lyrics and can recall them even if I haven't heard the song in years.

SCOR Southeast Clinical Oncology Research Consortium

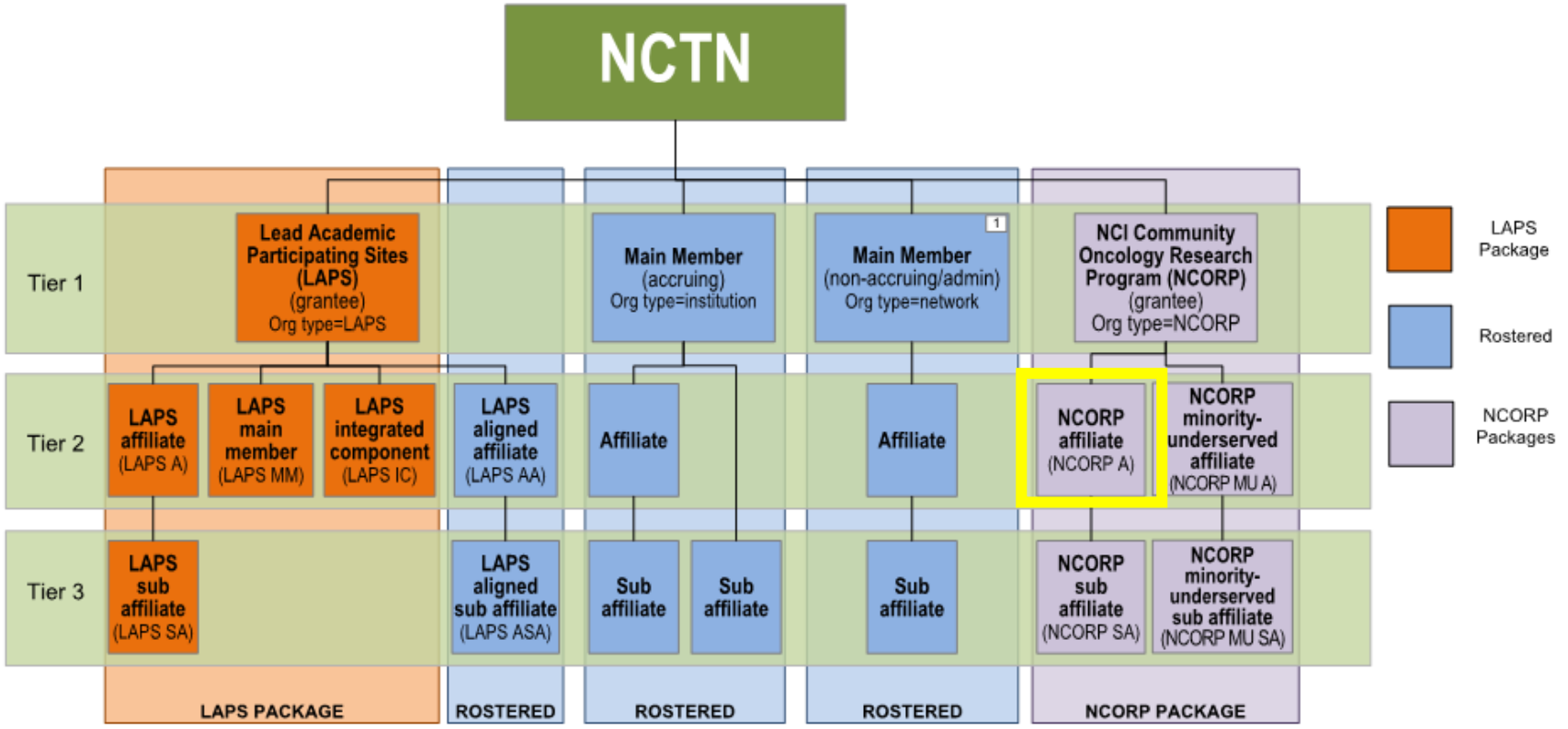
NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

SWOG CANCER RESEARCH NETWORK

NCI National Clinical Trials Network
a National Cancer Institute program

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

Where is Your Membership Swim Lane?



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Jennifer Haynes, BSN, RN, OCN, CCRC

IRB Coordinator & Clinical Research Nurse, Margaret R. Pardee Memorial Hospital

How do you onboard and train new regulatory coordinators?

I am the only regulatory coordinator at my site. When I started in the position, I was mentored by the previous person before she retired. I have also sought out external resources. There are currently no plans to expand our department.

How does your organization and membership structure impact your onboarding process?

There are currently no plans to expand our department. I am continually updating my processes so that anyone could pick up behind me.

Jennifer Haynes, BSN, RN, OCN, CCRC

IRB Coordinator & Clinical Research Nurse, Margaret R. Pardee Memorial Hospital

When you onboard a new coordinator, what tools do you use to stay organized?

I am updating my so that anyone could step in if needed. When there is a new research nurse hire in the department, they spend time with me learning all the processes that go into opening, maintaining, and closing studies.

When you were onboarded, what was the most helpful tip you received?

Don’t ever assume! Always ask. It is better to ask and learn something new. Change is inevitable so embrace it.

Jennifer Haynes, BSN, RN, OCN, CCRC

IRB Coordinator & Clinical Research Nurse, Margaret R. Pardee Memorial Hospital

How do you collect credentials at your institution? (i.e., GCP, CVs, IATA and/or bloodborne pathogens, RUMS, RCR, NCORP sys, CAPs and/or CLIAs of local laboratories, etc.)

I send out e-mails with the requests for items as well as placing notices on desks. Then I usually receive the materials via e-mail, or they bring them to my office.

Does your institution have SOPs regarding credentialing?

We have a process and procedure that we follow to ensure that all criteria are met.

Jennifer Haynes, BSN, RN, OCN, CCRC

IRB Coordinator & Clinical Research Nurse, Margaret R. Pardee Memorial Hospital

What tips and tools do you use to maintain credentials?

I keep a spreadsheet of expiration dates for these materials. I also check RCR monthly.

What systems do you have in place to prevent lapses in credentials?

I utilize my outlook calendar as well as a large wall calendar with all expiration dates.

Jennifer Haynes, BSN, RN, OCN, CCRC

IRB Coordinator & Clinical Research Nurse, Margaret R. Pardee Memorial Hospital

How do you organize and maintain essential documents throughout the trial? (i.e., CTMS, eRegulatory, shared drive, paper)

My site is currently in transition to an electronic system. When I started, it was all paper. I utilize binders and have scanned digital copies of all documents, so they are also electronically accessible. I still get wet signatures as well. I utilize a shared drive to store documents as well as ProIRB.

Do you have any tips or tools for the upkeep of amendments, submission deadlines, required documentation?

I use multiple spreadsheets, ProIRB software, shared calendars, and a paper calendar with dates written on it. I review the CTSU broadcast, SCOR update information, and I check in on the protocols when we have a new enrollment to ensure that we are up-to-date.

Jennifer Haynes, BSN, RN, OCN, CCRC

IRB Coordinator & Clinical Research Nurse, Margaret R. Pardee Memorial Hospital

How do you ensure PI oversight of essential documents?

My PI and I meet at least once a month to review the status of studies, including opening and closing. Documents that need more immediate attention are e-mailed to him or placed in his paper “in-box”. I then message him via Epic chat or text to let him know that I need expeditious signatures or oversight. If he needs more information, we frequently meet during his lunch break.

Why do you think knowledge about basic regulatory requirements are important to everyone’s individual role on the research team?

Regulatory is so important to the research process. It is key to keeping everyone safe and compliant. The more knowledgeable that all team members are regarding everyone’s individual role, the better the team can function. I know that if I understand why something is a certain way it is easier for me to handle.

Shawn England, MA, CCRP
Clinical Research Associate Sr.

Institution Name: University of Kentucky, Markey Cancer Center

SWOG Membership: Main Membership

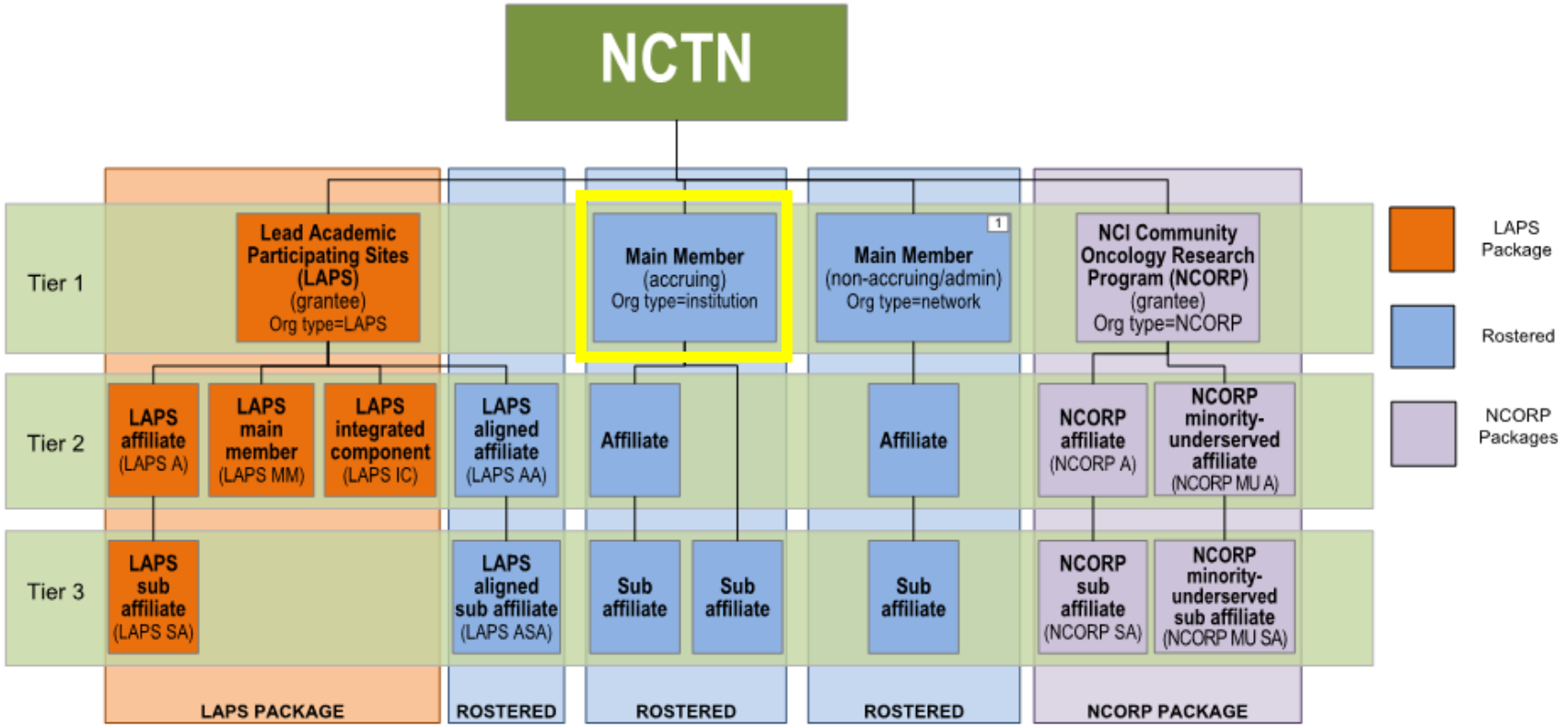
Number of affiliates: 5

Number of active trials: 323 active trials with 3 IRBs

Years Experience: 18 years of regulatory with 11 of these in cancer clinical research

Fun Fact: I have been collecting vinyl records since 1983. I have over 1,000 records from various genres (e.g., Rock, Hip Hop, Jazz, soundtracks, instructional records, sound effects, novelty, etc.)

Where is Your Membership Swim Lane?



1. Pre-approved for Main Member (non-accruing / administrative code) required for CTEP.

Shawn England, MA, CCRP
Clinical Research Associate Sr., UK, Markey Cancer Center

How do you onboard and train new regulatory coordinators?

We utilize an orientation checklist, and we have three senior regulatory coordinators that provide training and oversight.

How does your organization and membership structure impact your onboarding process?

We are main members. Our affiliate sites are managed by our research coordinating office and we have a designated regulatory coordinator that is responsible for onboarding new staff.

Shawn England, MA, CCRP
Clinical Research Associate Sr., UK, Markey Cancer Center

When you onboard a new coordinator, what tools do you use to stay organized?

We utilize checklists and maintain trackers (excel and OnCore notifications).

When you were onboarded, what was the most helpful tip you received?

- Never assume anything
- If it wasn't documented, it didn't happen
- Double check everything

Shawn England, MA, CCRP
Clinical Research Associate Sr., UK, Markey Cancer Center

How do you collect credentials at your institution? (i.e., GCP, CVs, IATA and/or bloodborne pathogens, RUMS, RCR, NCORP sys, CAPs and/or CLIAs of local laboratories, etc.)

We utilize email communication, tableau, CTSU registration and credentialing repository, and state licensure websites.

Does your institution have SOPs regarding credentialing?

We have working instructions and a separate investigator guide.

Shawn England, MA, CCRP
Clinical Research Associate Sr., UK, Markey Cancer Center

What tips and tools do you use to maintain credentials?

- Maintain trackers (excel and OnCore notifications)
- Share drive for central storage

What systems do you have in place to prevent lapses in credentials?

- Automated reminders from CTSU and OnCore
- Check manual trackers monthly and send out reminders

Shawn England, MA, CCRP
Clinical Research Associate Sr., UK, Markey Cancer Center

How do you organize and maintain essential documents throughout the trial? (i.e., CTMS, eRegulatory, shared drive, paper)

We utilize hard copy binder(s), Share Drive, OnCore, and IDS.

Do you have any tips or tools for the upkeep of amendments, submission deadlines, required documentation?

We conduct weekly reviews of CTSU postings and CR submission deadlines. Each regulatory coordinator maintains trackers for amendments.

Shawn England, MA, CCRP
Clinical Research Associate Sr., UK, Markey Cancer Center

How do you ensure PI oversight of essential documents?

We utilize monthly disease team meetings, email, and one on one meetings.

Why do you think knowledge about basic regulatory requirements are important to everyone's individual role on the research team?

The goal of clinical research is to improve the health and lives of our patients and to forward our understanding of disease. Regulation provides a common framework for the collection of data and the management of trials. When every member of the team has a good foundation in these principles, we improve the quality of the data collected and the confidence we have in it. This helps ensure that we are always moving forward.

Closing Remarks

Please join us as we continue the conversation with the Oishi Panelists at the Open Forum *Regulatory 101* breakout session #1 at 12:30.

Thank you

Understanding the PMB

Presenter:

Matt Boron, RPh

National Institutes of Health
NCI/DCTD/CTEP/PMB

Understanding the PMB

NIH NATIONAL CANCER INSTITUTE

October 20, 2022
9:00AM to 12:00PM

What Does PMB Do?

- Agent Management
  - Agent ordering/distribution
  - Drug information resource for NCI IND agents
  - Distribution of Investigator Brochures / SDS
- Person Registration
  - Identity and Access Management (IAM)
  - Registration and Credential Repository (RCR)
- Site Code management
- Treatment Referral Center

PMB in the CTEP CORE system

Person Registration

- Identity and Access Management (IAM)
  - Basic identification to be part of NCI person database - Associate (A) role

    Contact: ctepreghelp@ctep.nci.nih.gov
  - ID.me
    - Identity verification
    - 2-factor Authentication

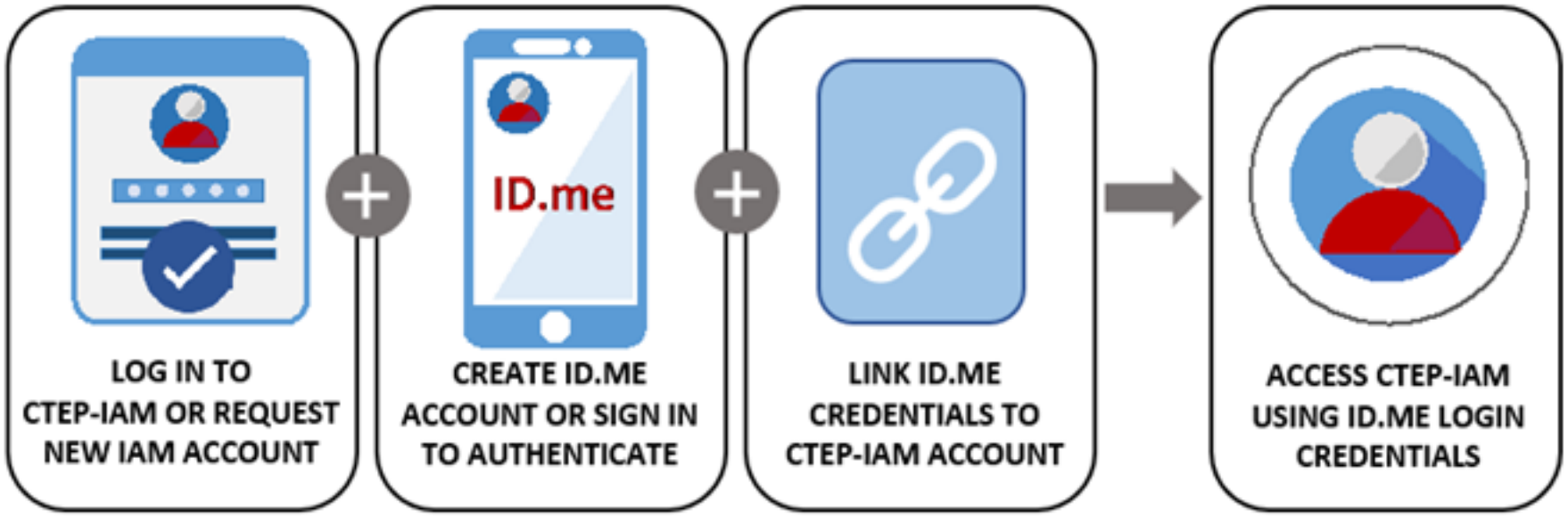
    Contact: CTEPHelpDesk@nih.gov

Enhanced IT Security required for all Federal Systems

- Identity verification and MFA is required for all federal systems and meets NIST SP 800-63-3 Digital Identity Guidelines
- Began July 8, 2022, CTEP-IAM integrated with ID.me to meet this requirement
- ***All users must complete ID verification and MFA with ID.me by July 1, 2023***

Making sure all users are who they say they are.

ID.me to IAM Workflow



For more information:
https://ctep.cancer.gov/investigatorResources/NCI_CTEP_IAM_User_Access_Update.htm

Person Registration

- Registration and Credential Repository (RCR)
  - Assignment of Registration Type (IVR, NPIVR, AP)
  - Collection of credentials
    - 1572
    - Biosketch
    - Financial disclosure
    - Shipping Address

Contact: RCRHelpDesk@nih.gov

Site Code Management

- Enterprise Core Module
  - CTEP Site codes
    - Research locations
    - Primary office and practice sites
    - Drug company codes
    - Drug shipment addresses

Contact: ecuhelpdesk@mail.nih.gov

Putting the Pieces Together

- Building rosters
  - Site
  - NCTN / ETCTN / LAPS
- Building your study team
- Completing your Delegation of Tasks Log (DTL)

Delegation of Tasks Log (DTL)

- Serves 2 main functions
  - Document study team
  - Allows delegation of tasks to study team members

- Completion of Site Protocol-specific package for FDA inspection

FDA 1572 Information Sheet: < https://www.fda.gov/media/78830/download >

Delegation of Tasks Log (DTL)

- Basic template comprised of 12 tasks
- Should list anyone making significant contributions to study conduct at the site
- Signed by the Clinical Investigator (CI)

Delegation of Tasks Log (DTL)

- Enhancements since release
  - Task Assignment browser
  - Bulk addition / deletion of tasks
  - Bulk signing for investigators
  - Working group to discuss possible enhancements

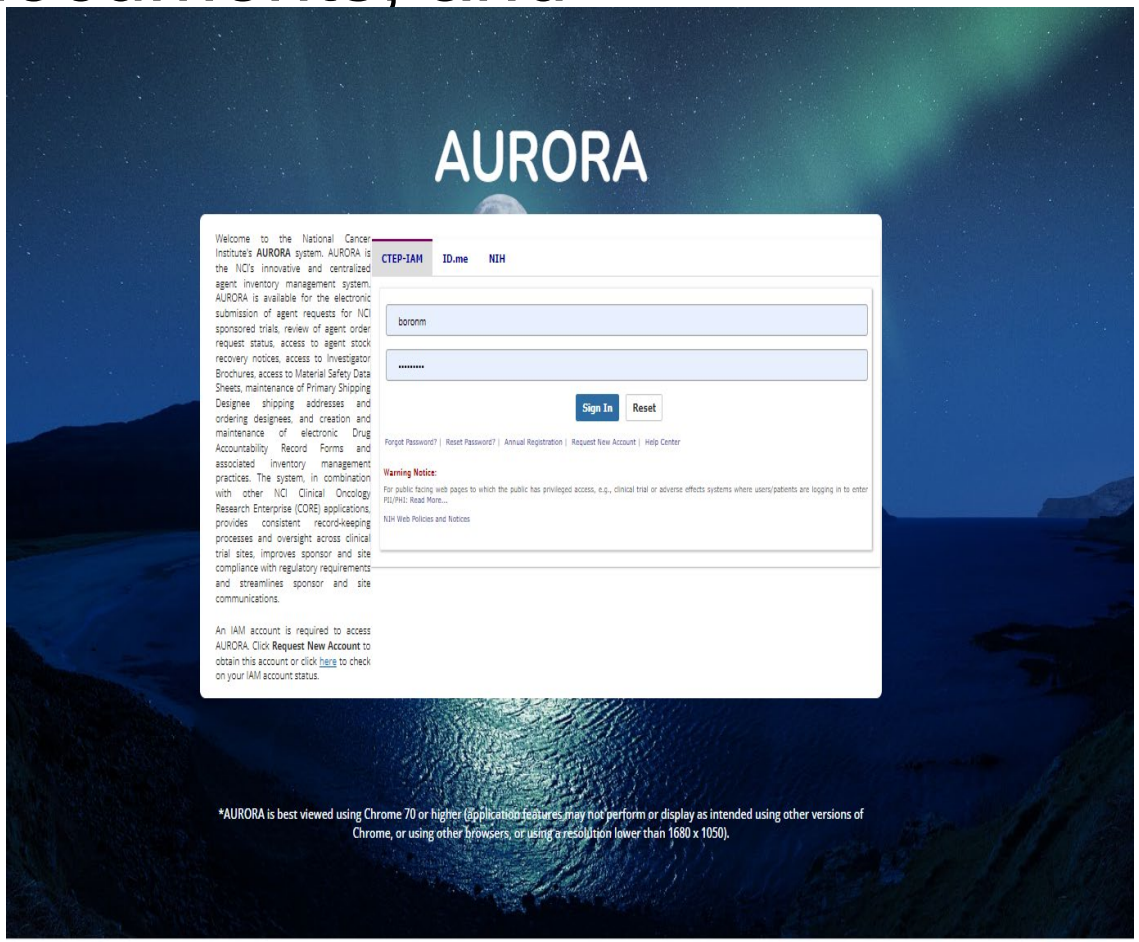
Agent Management

- Agent Management
  - Agent ordering/distribution
  - Drug information resource for NCI IND agents
  - Distribution of Investigator Brochures / MSDS

21 CFR 312 < https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=312>

AURORA

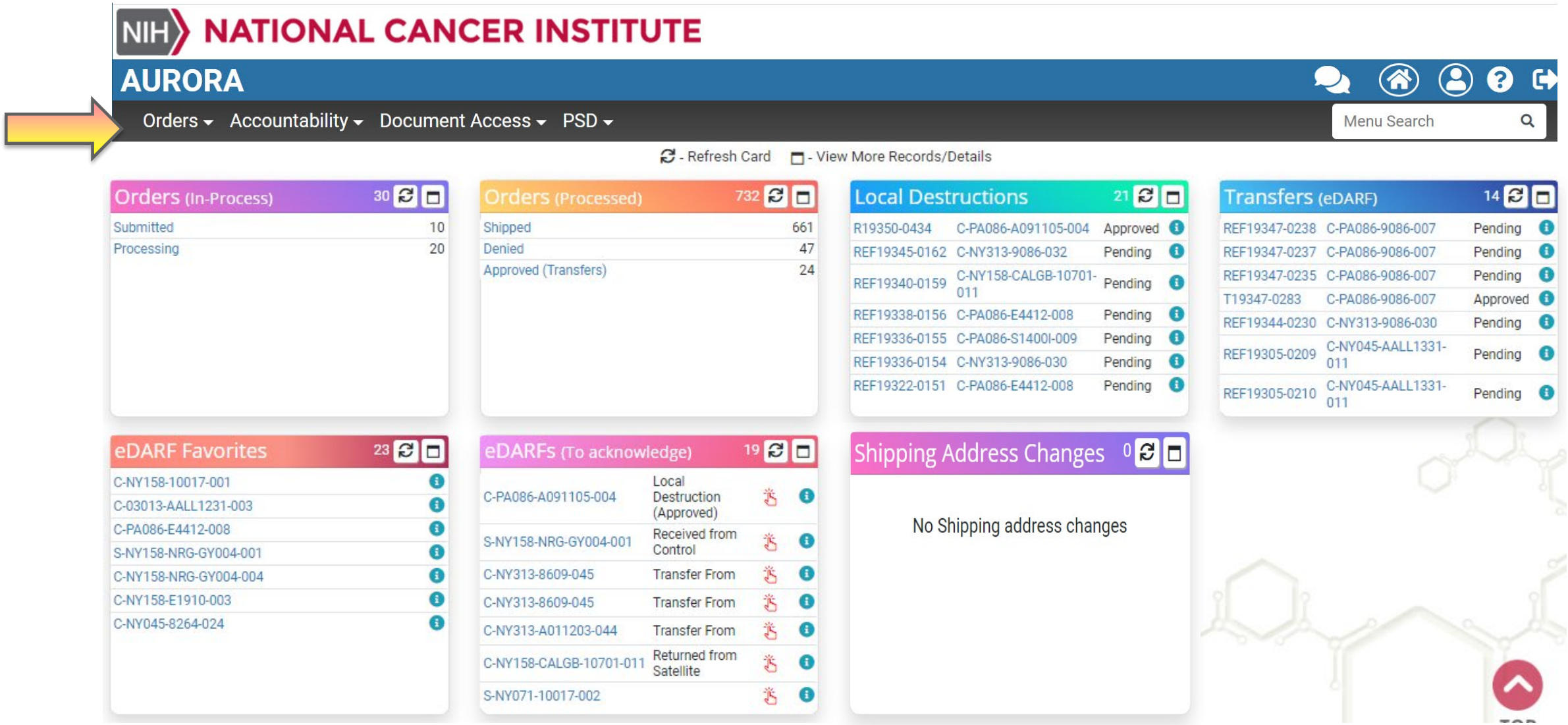
- Single system for PMB and sites to order agents/manage inventory, obtain agent related documents, and communicate
  - Replaces existing functionality
    - Ordering agents
    - Obtaining Investigator Brochures



AURORA

- Enhancements to plain old ordering application
  - Technology upgrade
  - Multiple Shipping addresses
  - Communicates with OPEN for patient enrollment information
  - First orders for blinded studies will now be **entered by the sites** through Aurora
  - Manage consistent shipping address – Primary Shipping Designee (PSD)
  - Direct communication with PMB
  - eDARF

AURORA Dashboard



AURORA resources

- All things AURORA PMB page:

  < https://ctep.cancer.gov/branches/pmb/aurora.htm >

  - Presentations
  - FAQs
  - AURORA Training Videos in CLASS (https://classlms.org)
- Embedded help in AURORA
  - Help button
  - Dialog button
- E-mail PMB – PMBAfterHours@mail.nih.gov

QUESTIONS??

General PMB questions: PMBAfterHours@mail.nih.gov

Matt Boron: Boronm@mail.nih.gov

Know Your IRBs

Facilitator: Joyce Nancarrow Tull, MSN, RN

Executive Director, Office of Clinical Research (OCR)

UC Davis Comprehensive Cancer Center

Know Your IRB Panelists

Introducing Our Panelists:

- CIRB Representatives Laura Covington and Jacqueline Steenbakker
- University of Kentucky Representatives Tosia Courtney, Shawn England and Stephanie Temple
- University of California Davis Representatives Ashley Tydon and Mary Gay Lapasaran
- Fred Hutchinson Representatives Maggie So and Melina Rodriguez
- Facilitator & Topic Consultants: Amy Koffarnus and Joyce Nancarrow Tull

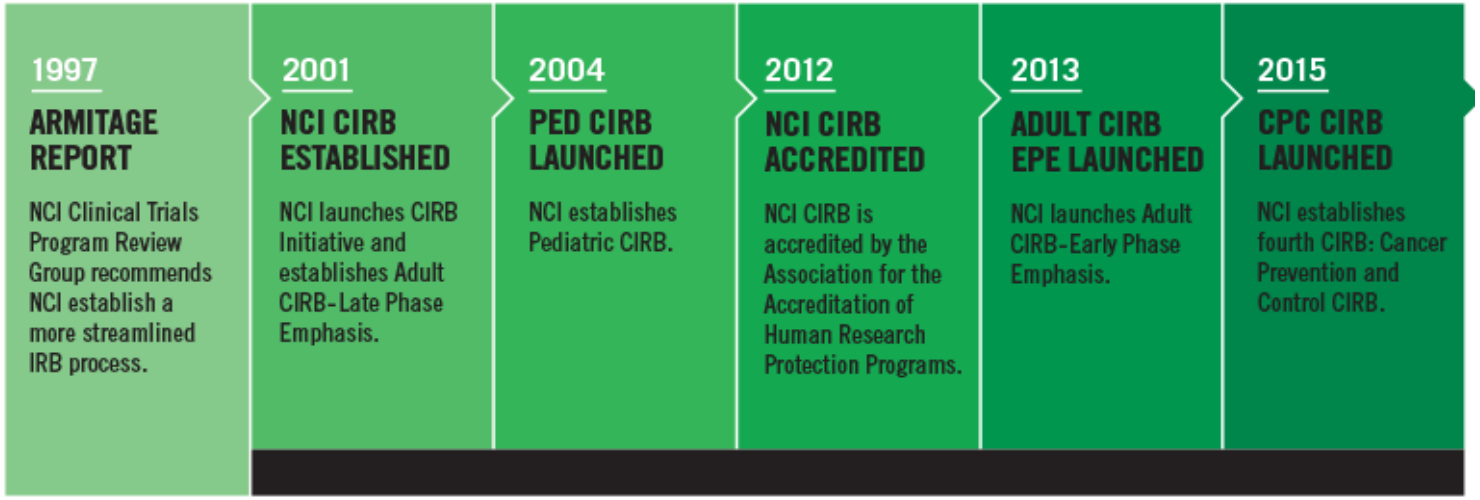
Know Your IRB: Why Regulatory Knowledge is Important

1. **Research is a TEAM activity**: Different constituents work together as a team to achieve compliant and safe research. It's important to understand the different constituents you work with and their role in the research team.
2. Their basic function is to review and monitor the human subject biomedical research you're operationalizing; they're watching over the research subjects to ensure their rights and welfare are protected.
3. It's important to understand what information and activities their responsibilities encompass and how the information you produce is a part of the review.
4. Regulatory work touches almost every aspect of the research process; knowing and understanding the "basics" of research regulatory information will help you be more successful in your specific role.

Know Your IRB: The NCI CIRB

Brief History & Evolution:

- Under the direction of the NCI, for NCI network multi-center, cooperative group or intergroup trials
- Accredited by AAHRPP
- More history and background at Welcome to the CIRB | NCICIRB



Know Your IRB: The NCI CIRB

The Authorization Agreement delineates what the CIRB does and what the institutions do.

CIRB

Initial, continuing, and amendment review

Local context for enrolled institutions

Trial-wide potential unanticipated problems and serious or continuing noncompliance (UP/SCN)

Locally-occurring potential UP/SCN

Review of studies that have an enrolled participant that become incarcerated while on study

INSTITUTION

Oversight of the research at the enrolled institutions

Adequate staff and resources are available to the PI

Identification and reporting of locally-occurring UP/SCN

HIPAA

Know Your IRB: The NCI CIRB

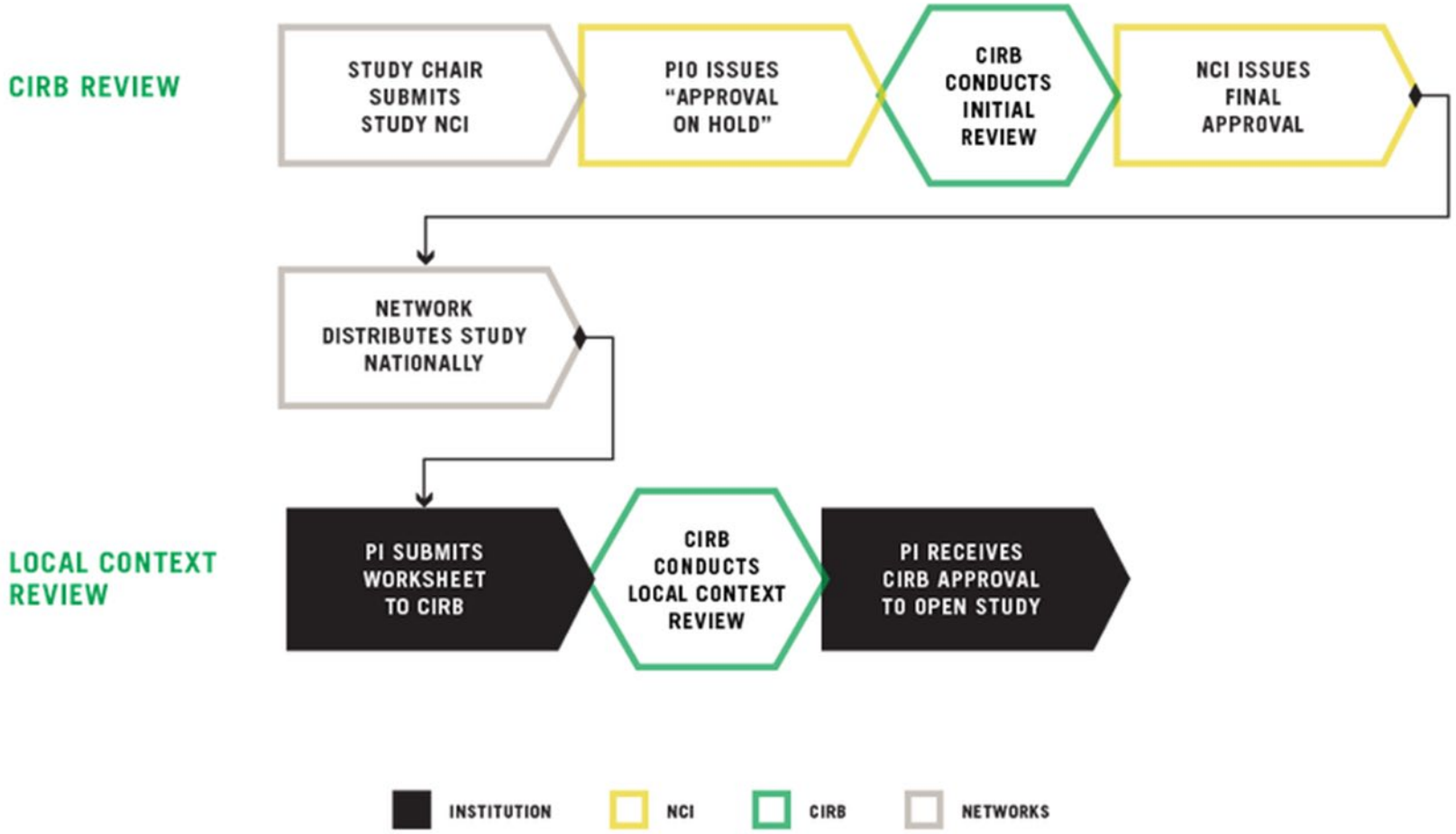
Local context considers:

- Local population for any unique requirements and protections for the institution's vulnerable populations
- Investigator resources
- Confirmation that boilerplate language for the consent form complies with the federal regulations

Established through:

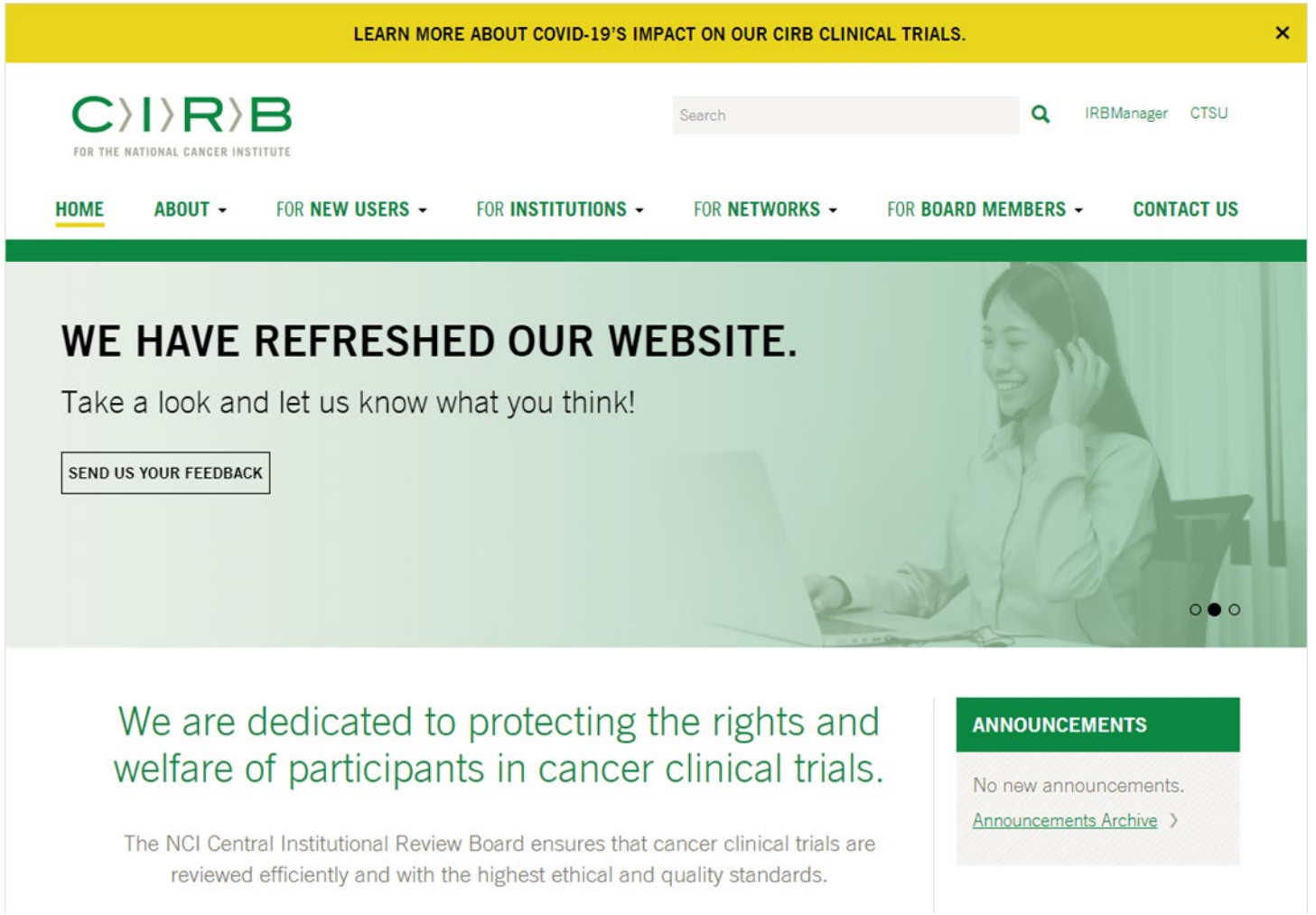
- Annual Signatory Institution Worksheet
- Annual Principal Investigator Worksheet when the PI is ready to open a study, the PI must submit a Study-Specific Worksheet to confirm the status of local context

Know Your IRB: The NCI CIRB

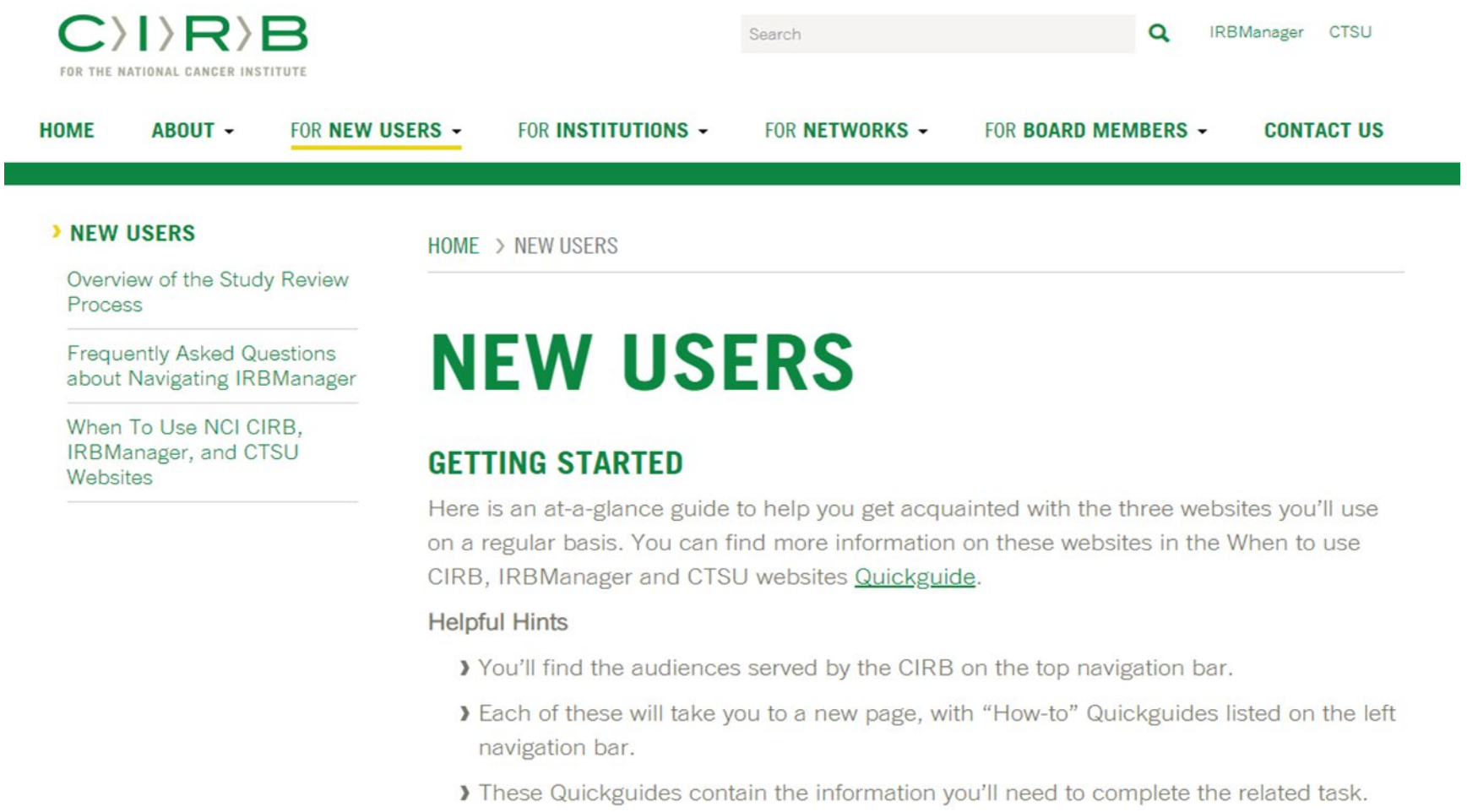


Know Your IRB: The NCI CIRB

[CIRB website]



Know Your IRB: The NCI CIRB



Know Your IRB: The NCI CIRB

CIRB WEBSITE	CTSU WEBSITE	IRBMANAGER
What You'll Find Here		

› General information about the CIRB
› How to use the CTSU and IRBManager websites
› "How-to" guides (called Quickguides) on filling out worksheets in IRBManager
	› Study-related and enrollment information
	› CIRB-related study documents
	› Roster Update Management System (RUMS)
	  › Make changes to your Signatory Institution's CIRB roster
		› Worksheets required by the CIRB
		› User Dashboard
		  › Studies open at your institution
		  › PI responsible for each open study at your institution
		  › Worksheets submitted by you, or by anyone at your institution

Know Your IRB: Our Local IRBs

- Everyone is unique, individual, and if you've worked with one, *you've worked with ONE*.
- There is a spectrum of IRB oversight with requirements that varying levels of requirements and oversight.
- Each Regulatory staff member must become familiar with and ascertain:
  - How your local IRB interacts with NCI CIRB and the conduct of NCI research
  - How institutional compliance policies intersect with NCI CIRB
  - Have the goal of developing an ongoing relationship which will support successful interactions and work
  - The "peculiarities and proclivities" of your institutional IRB

Know Your IRB: Basic Knowledge for Commercial IRB

- Commercial IRB work is predominantly for Industry potentially with some Institutional protocols
- Some of the current vendors for this service include WCG, Advarra, Brany, and Sterling.
- Affiliated groups such as NSABP Foundation, PRECOG, and ACCRU use these IRBs.
- SWOG may be moving to industry partnerships so may use more commercial IRBs in future state.
- A “meet and greet” setting expectations, policy awareness, providing guidance, and establishing a contact person are strategies which can assist in work

Laura Covington, MS
CIRB Co-Director

Institution Name: The Emmes Company holds the contract for support of the NCI CIRB

Types of trial you work on and number you manage: The CIRB has 842 studies for the NCTN, ETCTN, and NCORP as well as some smaller groups.

Years Experience: 16 years with the CIRB, 20 years of IRB experience, and 25 years of regulatory experience, including FDA submissions

Contact Information: ncicirbcontact@emmes.com or 888-657-3711 and address the query to Laura Covington

Fun Fact: I have always driven 2-door red cars. My current car is my dream car – a Fiat Spider convertible.

Jacquie Steenbakker, MSJ
CIRB EPE/LPE Administrator

Institution Name: The Emmes Company holds the contract for support of the NCI CIRB

Types of trial you work on and number you manage: 234 Early Phase studies and 344 Late Phase studies

Years Experience: 9 years with the CIRB and 21 years of IRB experience

Contact Information: earlyphasecirb@emmes.com (EPE) or adultcirb@emmes.com (LPE)

Fun Fact: I am a die-hard Chicago Cubs fan

Site Name: NCI CIRB
IRB Specialty Area: Central IRB

1. What tips and tricks, quirks, and nuances have you learned while completing regulatory work at your site?

The CIRB website (ncicirb.org) has been updated and has a lot of information on how to do the most common tasks with the CIRB. Many of the tricks and nuances for working with the CIRB can be found there.

Site Name: NCI CIRB
IRB Specialty Area: Central IRB

2. What did you learn during the pandemic (i.e. on remote consenting or relaxed approvals)?

Remote consent was implemented for the pandemic and the CIRB is currently working on policies that will continue after the pandemic for remote consent.

Site Name: NCI CIRB
IRB Specialty Area: Central IRB

3. What actions do you take at your site to establish a good working relationship with the IRBs?

Sites have an assigned local context coordinator (LCC) to help them with their submissions to the CIRB. The CIRB Helpdesk is available for general questions or for sending queries to specific people within the CIRB Operations Office.

Shawn England, MA, CCRP
Clinical Research Associate Sr.

UK HealthCare
MARKEY CANCER CENTER
An NCI-Designated Cancer Center

Institution Name: University of Kentucky, Markey Cancer Center

SWOG Membership: Main Membership

Types of trials you work on and number you manage and IRBs you work with: NCI Cooperative, Foundation, Industry and Investigator Initiated.

323 active trials and work with 3 IRBs

Years Experience: 18 years of regulatory with 11 of these in cancer clinical research

Fun Fact: I have been collecting vinyl records since 1983. I have over 1,000 records from various genres (e.g., Rock, Hip Hop, Jazz, soundtracks, instructional records, sound effects, novelty, etc.).

Site Name: University of Kentucky Markey Center
IRB Specialty Area: Local UK IRB

1. What tips and tricks, quirks, and nuances have you learned while completing regulatory work at your site?
   - Learning to utilize our CTMS (OnCore)
   - Learning about who does what and when
   - Learning the best communication method with our Investigators

Site Name: University of Kentucky Markey Center
IRB Specialty Area: Local UK IRB

2. What did you learn during the pandemic (i.e. on remote consenting or relaxed approvals)?
    - Adapting new processes to remote work
        - Communications (teams, zoom, text)
        - Additional steps needed to consent hospitalized COVID positive patients
        - Electronic signatures
        - Remote audits

Site Name: University of Kentucky Markey Center
IRB Specialty Area: Local UK IRB

3. What actions do you take at your site to establish a good working relationship with the IRBs?
   - Proactive communication
   - When in doubt-reach out for guidance
   - Recognition

Ashley Tydon
Clinical Research Director, Cancer Care Network

Institution Name: UC Davis Comprehensive Cancer Center

SWOG Membership: LAPS main member, integrated component and affiliate

Types of trials you work on and number you manage and IRBs you work with: All types

Years Experience: 15 years (2+ years overseeing a regulatory unit)

UCDAVIS HEALTH | COMPREHENSIVE CANCER CENTER

Contact Information: atydon@ucdavis.edu

Fun Fact: I am an old home and antique enthusiast.

Mary Gay Lapasaran, MD, ACRP-CP
Senior Regulatory Coordinator

Institution Name: UC Davis Comprehensive Cancer Center

SWOG Membership: LAPS main member, integrated component and affiliate

Types of trials you work on and number you manage and IRBs you work with: Industry, Investigator-Initiated, Federal – mainly local IRB, Reliance IRB, and Commercial IRB

Years Experience: 7 years in clinical research, 2.5 years in regulatory

Contact Information: mlaparasan@ucdavis.edu

Fun Fact: I have an identical twin sister on the other side of the world☺

Site Name: UC Davis Comprehensive Cancer Center
IRB Specialty Area: NCI CIRB, local/commercial IRB

1. What tips and tricks, quirks, and nuances have you learned while completing regulatory work at your site?
   - Develop standard operating procedures, guidelines and checklists
   - Standardize naming conventions of all documents
   - Develop communication plans
   - Stay FLEXIBLE

Site Name: UC Davis Comprehensive Cancer Center
IRB Specialty Area: NCI CIRB, local/commercial IRB

2. What did you learn during the pandemic (i.e., on remote consenting or relaxed approvals)?

- The pandemic forced a conversation about and openness to leveraging the technology available to us
- Helped push the effort ahead to allow new methods of our work

Site Name: UC Davis Comprehensive Cancer Center
IRB Specialty Area: NCI CIRB, local/commercial IRB

3. What actions do you take at your site to establish a good working relationship with the IRBs?

- Talk to your IRB! Set up a routine, standing meeting with IRB administrative leadership
- Give them feedback! Its important they hear from their end-users. Cancer centers are often the “BMOC” and can illuminate problems and provide input on process improvements.

Melina Rodriguez, BS
Regulatory Coordinator

FRED HUTCH / UNIVERSITY OF WASHINGTON / SEATTLE CHILDREN'S
CANCER CONSORTIUM

Institution Name: Fred Hutchinson Cancer Center

SWOG Membership: LAPS - FHCC

Types of trials you work on and number you manage and IRBs you work with: Full range of studies but mostly interventional clinical trials;

Years Experience: 6 years in public health + oncology research, including 2 years in regulatory

Contact Information: mrodrig3@fredhutch.org

Fun Fact: I took up embroidery during the pandemic and it's become my favorite pastime

Site Name: Fred Hutchinson Cancer Center
IRB Specialty Area: NCI CIRB, Fred Hutch IRB & UW HSD

1. What tips and tricks, quirks, and nuances have you learned while completing regulatory work at your site?
   - Fostering relationships with support staff (admins, managers, etc.)
   - Leaning into technology
     - Adobe Digital eSignatures
     - Florence eBinders
     - Microsoft Teams' channels to streamline updates, house internal training/DOA trackers, and NCTN regulatory work guides/tutorials; continuity is a plus; quick touch base chats with CRCs

Site Name: Fred Hutchinson Cancer Center
IRB Specialty Area: NCI CIRB, Fred Hutch IRB & UW HSD

2. What did you learn during the pandemic (i.e., on remote consenting or relaxed approvals)?
   - Remote consent and telehealth
     - Devil is in the details; submissions must provide clarity on stage of consent, reconsent, follow up, or who will be consented, etc.

Site Name: Fred Hutchinson Cancer Center
IRB Specialty Area: NCI CIRB, Fred Hutch IRB & UW HSD

3. What actions do you take at your site to establish a good working relationship with the IRBs?

- Reaching out to the IRB when we have questions or need clarity, prior to submission
- Aiming to be quick on communication, turn around times

Wrap-Up!

- This conversation will continue in Open Forum: Know Your IRB.
- Our panelists will be available for connection, conversation, questions, and to explore further areas of interest related to IRBs.

THANK TO ALL OF

THE WONDERFUL PANELISTS!!

SWOG Perspectives

Dana Sparks

SWOG Operations & Protocols Director

Cara Laubach

SWOG Operations Office Training Manager

Elaine Armstrong, MS

Retired! ☺ … SWOG Operations Office Quality Assurance Consultant

Laura Gonzales, BSN, MA, RN, OCN

SWOG Operations Office Quality Assurance Manager

Maggie Spillers, BSN, RN

SWOG Operations Office Quality Assurance Assistant Manager

SWOG Perspectives and Common Challenges

Regulatory Intersection and Available Resources

NCI and SWOG: Regulatory Intersection

NIH Standards of Conduct:

"The NIH depends on the funded research community to utilize a system of self-regulation coupled with appropriate NIH oversight. Ethical concerns, such as human subjects protection (45 CFR Part 46), promotion of animal welfare (P.L. 99-158 Section 495), removal of financial conflict of interest (42 CFR Part 50, Subpart F), and prevention of scientific misconduct (42 CFR Part 50, Subpart A) are all a part of this self-regulation.

The principle of self-regulation requires a high level of trust in the fundamental integrity of the research community and sufficient oversight to enable the NIH to assure the public that self-regulation is providing adequate safeguards for the ethical integrity of science."

~By accepting an award, grant recipients agree to comply with the requirements in the NIH Grants Policy Statement except where the notice of award states otherwise.

NCI Investigator's Handbook

Studies conducted under SWOG-held INDs

For studies conducted under a SWOG-held IND:

- See protocol Section 3 for drug supply/distribution and disposition instructions (dependent upon the industry contract).
- Unless otherwise stated in the protocol, SWOG utilizes Section 3.0 of the protocol as the Investigator's Brochure, per SWOG Policy 15. In rare cases where the local institution requires the IB, SWOG will convey the request to the industry collaborator; The industry collaborator may require the participating site to execute a confidentiality disclosure agreement directly with the company to obtain the IB.
    - Exception to this is LungMAP or other studies where SWOG holds the IND but PMB does the drug distribution.

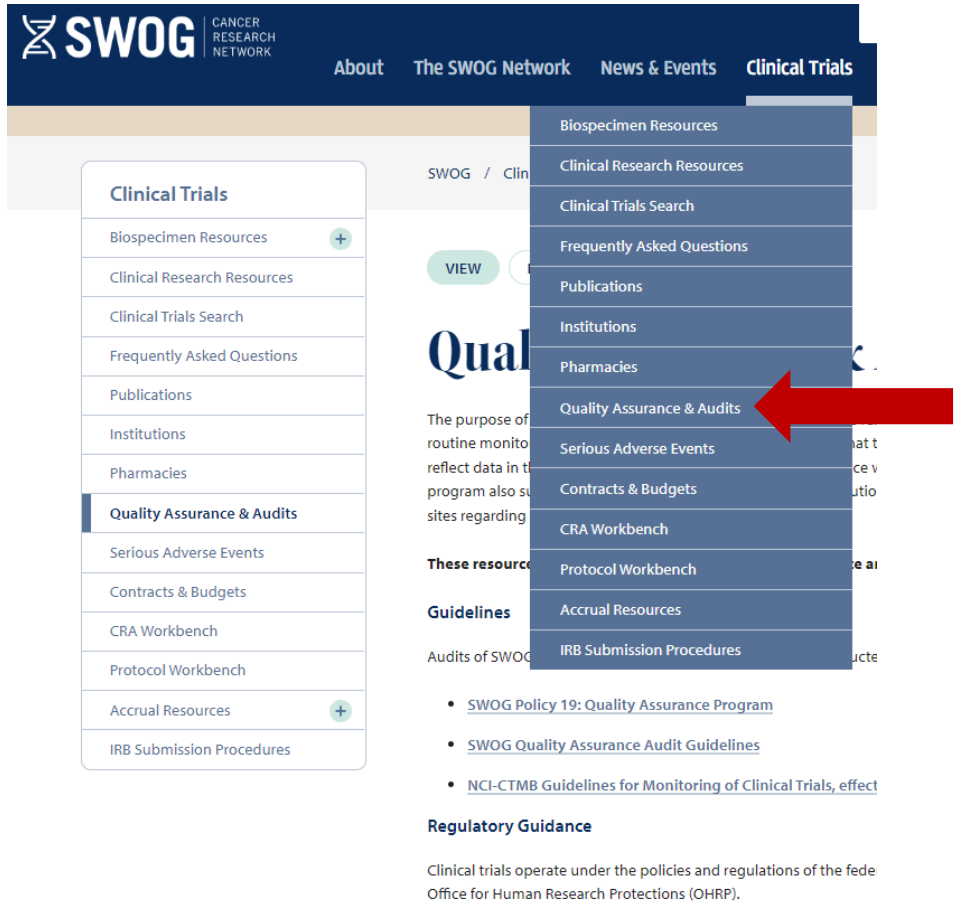
SWOG Policies, Procedures, and Guidelines

- SWOG Policies:

Policy 12	SWOG Registration and Treatment Policies
Policy 15	Applicability of IND Applications and Investigator Brochures/Support From Pharmaceutical Companies
Policy 18	Data Evaluation Policy and Procedure
Policy 19	Quality Assurance Program
Policy 20	New Agent Studies and Safety Monitoring
Policy 21	Data and Safety Monitoring
Policy 22	Ethical and Regulatory Considerations
Policy 23	Serious Adverse Events
Policy 25	Drug Ordering
Policy 29	Roster of Investigators Maintenance Policies and Procedures
Policy 30	Responsibility for Patient Follow-Up
Policy 33	Institutional Performance Review
Policy 36	Affirmation of Integrity
Policy 38	Research Calculations for Clinical Trials
Policy 39	Acquisition, Maintenance and Use in Research of Tissue and Other Biologic Patient Specimens

SWOG Best Practices and Quality Assurance

- 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



Training Courses and Supporting Resources

- ExpertusONE LMS
  - Login with CTEP IAM credentials
  - In particular note following for regulatory guidance:
    - Audits-Quality Assurance, Ethics in the Conduct of Clinical Trials, and Investigational Agent Handling Training courses/modules.
  - *Forthcoming soon:* Regulatory Considerations in Oncology Research (Overview presentation)

- New "Onboarding" resource list, accessible from the SWOG Clinical Research Resources: Resources for Oncology Research Professionals

- CRA Workbench
  - *"Popular Resources":* SWOG QA / Monitoring, SWOG Best Practices
  - *"Resources"*
    - Common Terminology Criteria for Adverse Events (CTCAE),
    - CTEP guidance for AE start/stop dates
  - CRA Manual for Oncology Research Professionals: By chapter (detailed procedural guidance)
  - *"Tools":* Clinical Trial Review Guide

SWOG 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 Perspectives and Common Challenges

Quality Assurance Perspective

Long-Term Follow-up

- SWOG Policy for LTFU
  - Resources: ORP Manual Chapter 10 and SWOG Policy #30.

- Regulatory requirement: Studies must remain open until added to the ***List of SWOG Studies with No Required Follow-up*** Report. This applies even if no patients remain in follow-up locally.

- Long-term Follow-up Protocol **S9808**
  - A tool to simplify the process of obtaining annual review for multiple LTFU studies. Only applicable to studies that continue with local IRB as the IRB of record
  - Studies open through CIRB should not be transitioned LTFU protocol
  - Resource:
    SWOG List of studies for S9808 – Long-Term Follow-up Protocol Report

Patient Transfers

- Patients on treatment: The ‘receiving’ institution must have current IRB approval of the protocol prior to accepting a transfer.
- Patients in follow up: The transfer may occur prior to IRB approval of the protocol as long as the ‘receiving’ institution agrees to obtain approval prior to conducting any research activities involving the new patient(s). In this case, expedited review of the protocol for follow-up activities only is sufficient.
- The site initiating a transfer should resolve all outstanding expectations and queries and provide a copy of the research record to the ‘receiving’ institution PRIOR to initiating a patient transfer.

Patient Transfers

- Transfer patients must sign a new consent form and HIPAA authorization at the new institution.
- If a transfer patients is audited, the audit will be conducted at the ‘receiving’ institution. The ‘receiving’ institution should ensure receipt of a copy of the research record prior to accepting the transfer as all data submission and corrections must be performed by the ‘receiving’ institution after the transfer.
  - Resources: SWOG Policy #30
  - Questions?
    - patienttransfer@swog.org;
    - CTSU Helpdesk: CTSUContact@westat.com

Protocol deviations

- SWOG follows CIRB guidance on reportability of protocol deviations for sites using both a local IRB or the CIRB
- Report potential unanticipated problems and/or non-compliance per CIRB guidelines to the IRB and SWOG (qamail@swog.org) and include a corrective and preventive action plan
- SAEs that meet the definition of “unanticipated” (serious [Grade 3 – 5], unexpected and at least possibly related must be reported to the IRB
- Report major audit findings as potential serious noncompliance
    - See: Algorithm to Assess a Potential Unanticipated Problem
    - See: Algorithm to Assess Potential Noncompliance

Involvement of Outside Facilities / non-CTEP Registered Providers

- Investigator Handbook (see Section 14): CTEP discourages the administration of SOC treatment by local physicians unless the treating investigator maintains very careful surveillance.
- SWOG requirements:
  - SWOG Policy 12: Patients must not be registered if they will not be seen at the institution reported as the 'treating institution'. In rare cases, circumstances developing after registration may require that a patient receive care from a non-SWOG physician. This does not release the registering investigator from the responsibilities noted above.
  - SWOG Policy 30: All institutional and individual participants in SWOG are responsible for the follow-up of all patients registered by the institution and/or the individual at the institution for as long as the patient remains alive (or for a protocol specified length of time).

Involvement of Outside Facilities / non-CTEP Registered Providers

- DTL requirements for FDA registration studies and studies utilizing investigational agents: list of tasks that must be performed by CTEP providers or other research staff that have been assigned these tasks by the site PI.
- After COVID provisions retired (currently set for December 2022): 1. Outside facility allowances must be specified in protocol. 2. Non-CTEP Registered Providers (investigators) may only be utilized as specified in the protocol.
- Going forward: Telehealth allowances will be considered by study team for incorporation into the protocol.
- The registering/treating investigator retains the responsibility for all patient care, protocol evaluations and data collection.
- Sites are responsible for making arrangements to obtain documentation from outside providers to support all research activities in order to facilitate protocol assessments, timely data submission and audits.
- If unable to obtain required documents after multiple attempts, all research activities must return to the registering site.

Involvement of Outside Facilities / non-CTEP Registered Providers - Allowances

- Eligibility/pre-registration:
  - Labs
  - Scans
  - Pathology
- On treatment/intervention:
  - Labs
  - Scans
  - RT (when protocol does not require a credentialed RT site)
  - Surgery (when protocol does not require a credentialed surgical site/surgeon)
- Long term follow-up:
  - Labs
  - Scans
  - H&P assessments (DTL) if final assessment performed of patient status performed by research site

Audit Preparation for Regulatory Audit - CIRB

What documentation IS needed:

- A copy of the initial CIRB Approval of the Study-Specific Worksheet About Local Context giving approval to conduct the study and subsequent revisions, if applicable,
- Documentation of local implementation date for protocol updates and ALL informed consent versions.
- Copy of ALL versions of locally implemented consent forms, including local updates (e.g., PI change) or a comprehensive list of all versions.
- For studies that do not have a DTL, a copy of the local Site Authority Log. If DTL, auditor will verify online.
- Copy of the Trial Master File (if registration study).
- Resource: SWOG Regulatory Audit Guidelines

- What documentation is NOT needed:
  - CIRB review/approval documentation that is available on the CTSU website for all sites, including:
    - CIRB initial and continuing review approvals of the protocol,
    - Amendment approvals.

Audit Preparation for Regulatory Audit – Local IRB

Required documentation:

- Initial approval and continuing annual reviews.
- Approval of protocol modifications (amendments, revisions, action letters, etc.) and associated consent forms, if applicable.
- Submission of external safety reports reportable per local SOP within 90 days (10% verified at audit).
- Alternatively, a copy of local policy for alternate method for handling submission of external safety reports.
- Submission of internal Serious Adverse Events defined as unanticipated.
- Documentation must provide date of meeting/approval, item approved, protocol/consent versions, etc.
  - Copy of ALL versions of the locally implemented consent forms, including specimen collection/banking consents and HIPAA authorization documents (if separate) .
  - If study does not have a DTL, then copy of the local Site Authority Log. If DTL, auditor will verify online.
  - Copy of the Trial Master File (if registration study).
  - Resource: SWOG Regulatory Audit Guidelines

Audit Preparation for Patient Case Audit

Informed Consent: ICFs should be readily available for auditor review.

- This should also include reconsent documents and any notes discussing revisions that require patient notification.

Consent Withdrawal: Refer to SWOG Policy #30.

- If a patient withdraws consent after registration, the institution must determine *with the patient* whether
    1. They no longer wish to be treated per protocol
    2. They wish to no longer be followed per protocol, or
    3. Both.
- Withdrawing consent to participate in a study does not necessarily mean the patient also withdraws consent to being followed.
- QA recommends use of a Consent Withdrawal document that delineates patient's wishes. Document should be signed, dated, and kept in medical record, available for auditor review.
- Data must continue to be submitted per protocol for patients who have consented to follow-up. Refer to Protocol Sections 7, 9, and 14.

Audit Preparation for Patient Case Audit

Delegation of Task Log (DTL)

DTL is required for all FDA registration studies and for studies that utilize investigational agents.

Prior to audit, the DTL is reviewed on CTSU to ensure that it is active.

During an audit, the DTL will be spot-checked to make sure that the staff member who consents the patient, performs the H & P, etc., is listed on the DTL and authorized to perform the task.

Serious Adverse Event – Frequent Errors

- What to watch out for on Forms and Reporting scenarios
  - AE must be serious, must select seriousness criteria for each SAE
  - Send all AEs for evaluation using the Expedited Reporting Evaluation form
  - Rave recommendations are not a mandate to report
  - One CTEP-AERS ticket allowed per cycle
- What to watch out for in the Protocol (SPEER and reporting exceptions)
  - SPEER – exceptions to expedited reporting but not a mandate to report
  - AESI = AEs of Special Interest
  - Commercial agents – hospitalization not a determining factor
  - Unexpected = not a known potential adverse event for drug

Dose Modifications

- Things to watch for in the protocol:
  - Allowable windows are expressed in CALENDAR days
  - Importance of monitoring abnormal labs for potential dose modifications
    - Suggestion: AE log could note which lab AEs have required dose modifications
  - Standard of Care drugs used in the protocol in an investigational combination or frequency, or dose.
    - Refer to the protocol for instructions.
      - Sites must follow the protocol-specified dose modifications.
      - Institutional dose modifications are only allowable IF specified in the protocol.

Study Close-out

- For IRB/CIRB termination, the study must be included on the list of SWOG Studies with No Required Follow-up (“No follow list”)
  - Generally, after publication of primary results.
  - Resource: ORP Manual Chapter 10 and SWOG Policy #3

Drug Accountability and Disposition

- Transfers
- DARF
- Resources:
  - Current version of SWOG Protocol (Section 3) / NCTN Lead Group Protocol
  - CTEP Investigator's Handbook
  - Pharmaceutical Management Branch (PMB)
  - PMB Returning agent to NCI Clinical Repository (PDF) (06/14)
  - PMB Patient returns of oral clinical supplies (PDF) (12/13)
  - PMB Agent inventory discrepancy (PDF) (02/16)
  - PMB Investigational Drug Accountability Training Videos
  - PMB Reporting errors to PMB (PDF) (04/16)
  - PMB Satellite dispensing areas (PDF)

Oishi
Common Challenges
Panel Discussion

Facilitator: Amy Koffarnus, BS, CCRP
Research Administrator – CROWN Consortium

Amy Koffarnus, BS, CCRP
Research Administrator – CROWN Consortium

Institution Name: HSHS St. Vincent Hospital

SWOG Membership: NCORP site – CROWN Consortium

NCI CIRB: 3 unique NCI CIRB signatory institutions within the consortium

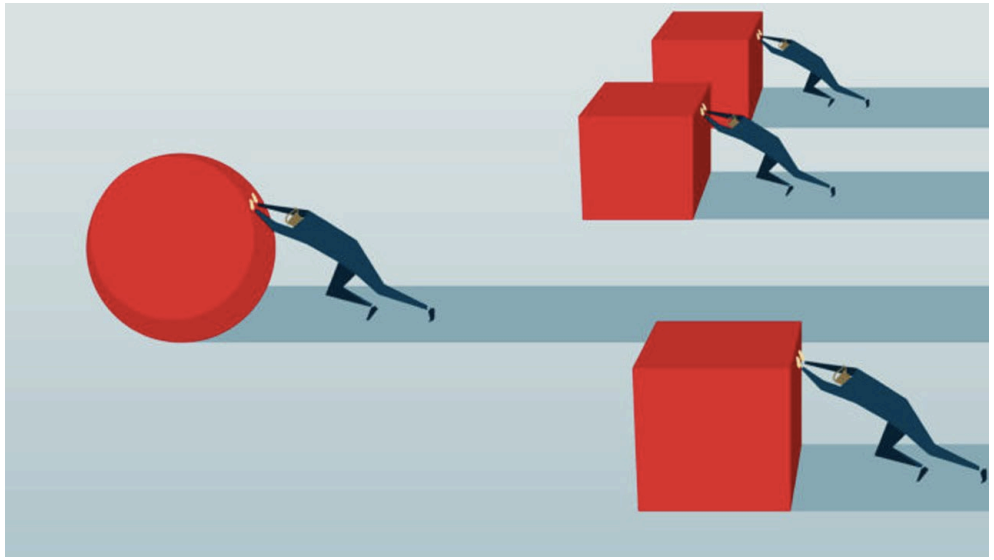
Number of affiliates: 29 affiliates across the consortium

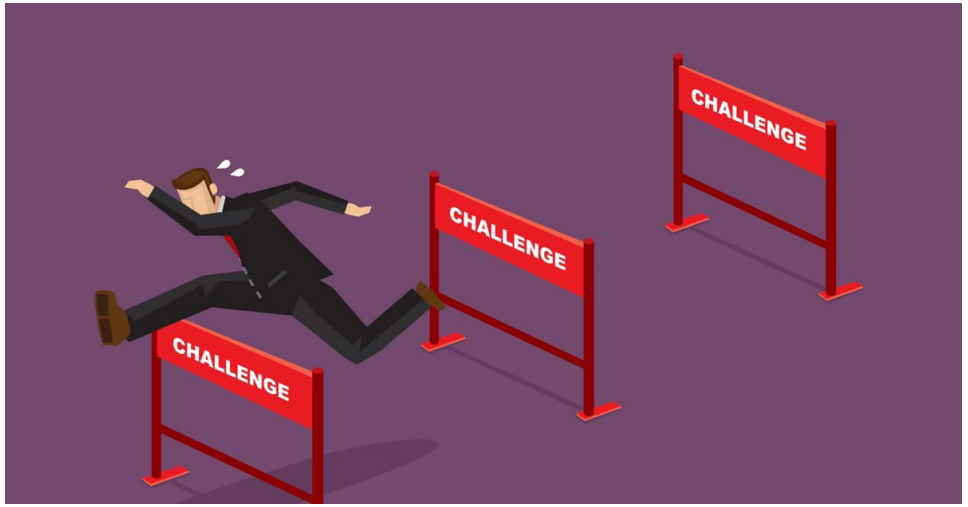
Number of active trials: 102 clinical trials across the consortium

Years Experience: 15 years in cancer research

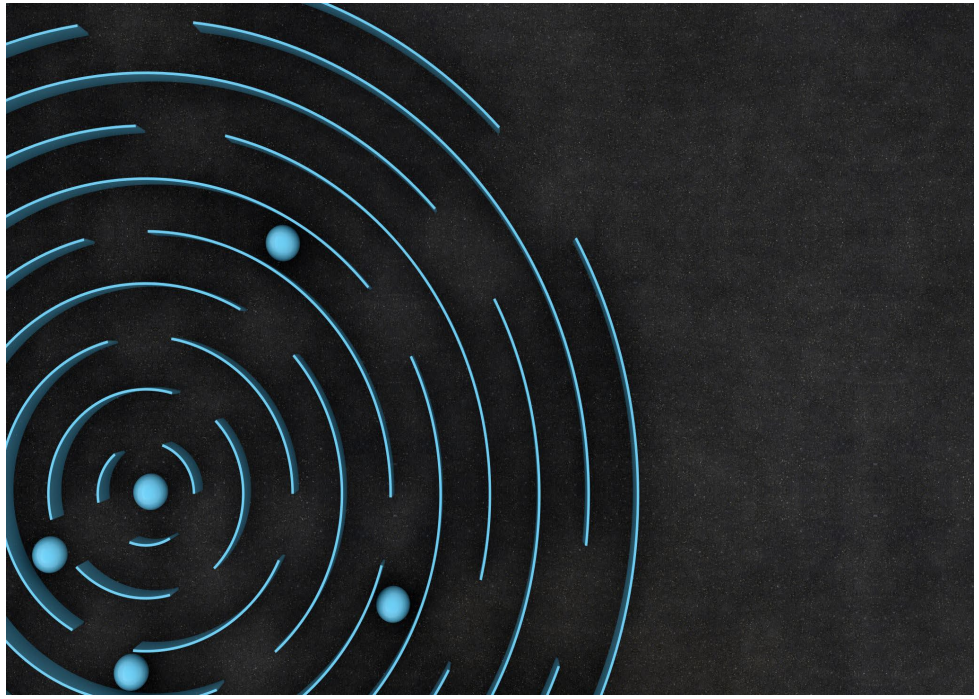
Fun Fact: My favorite pet is my chickens

Challenges: We all have them



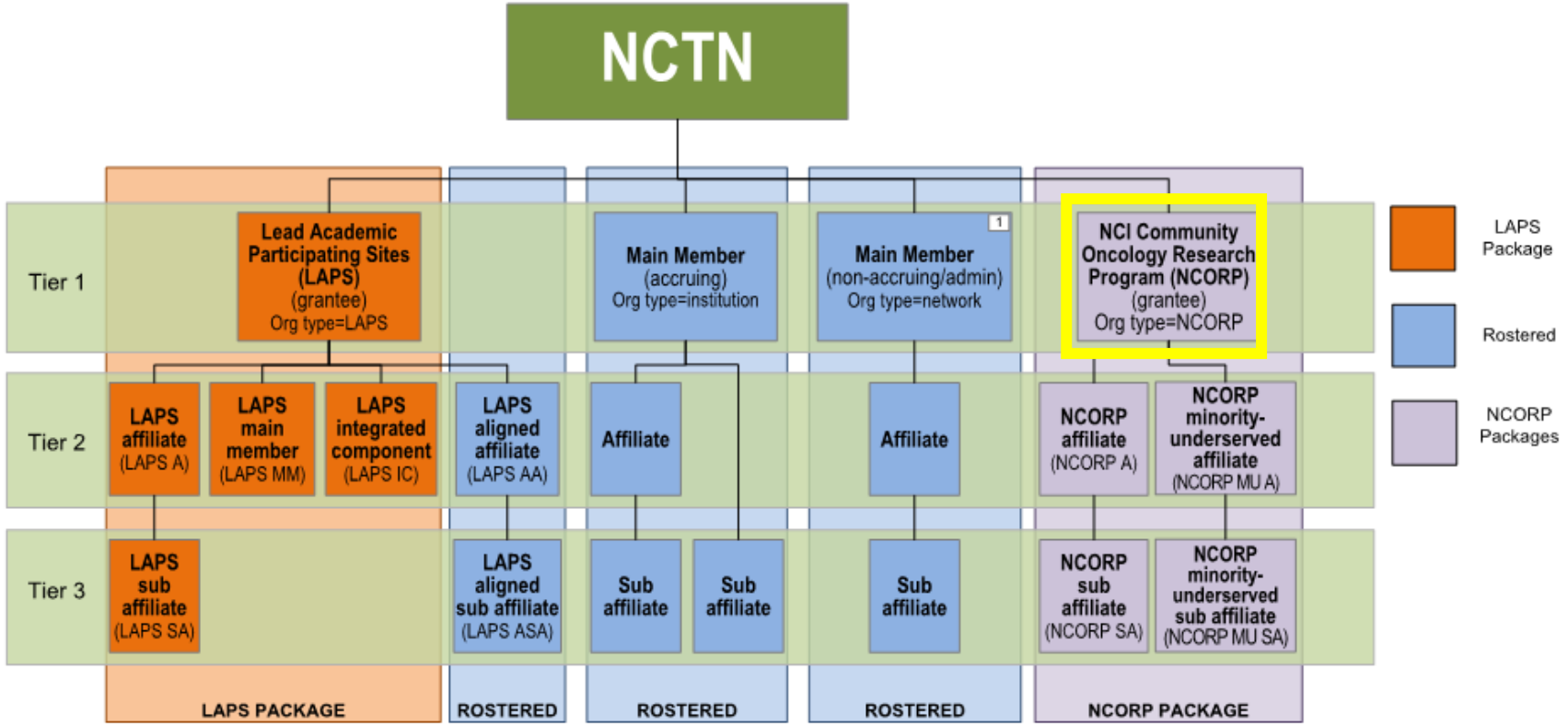


Solutions: Not always the same




One size does not fit all.
#boomerandbitsy
ANIMAL
EMERGENCY
& REFERRAL
CENTER
OF MINNESOTA
aercmn.com

Where is Your Membership Swim Lane?



1. Pre-approved for Main Member (non-accruing / administrative code) required for CTEP.

Caitlin Hutchinson, MS
Clinical Research Manager, Oncology

U.S. Department of Veterans Affairs
Veterans Health Administration
Eastern Colorado Health Care System

Institution Name: Rocky Mountain Regional VAMC

SWOG Membership: LAPS affiliate – University of Colorado Denver/Main member (convoluted historical relationship)

NCI CIRB: 1

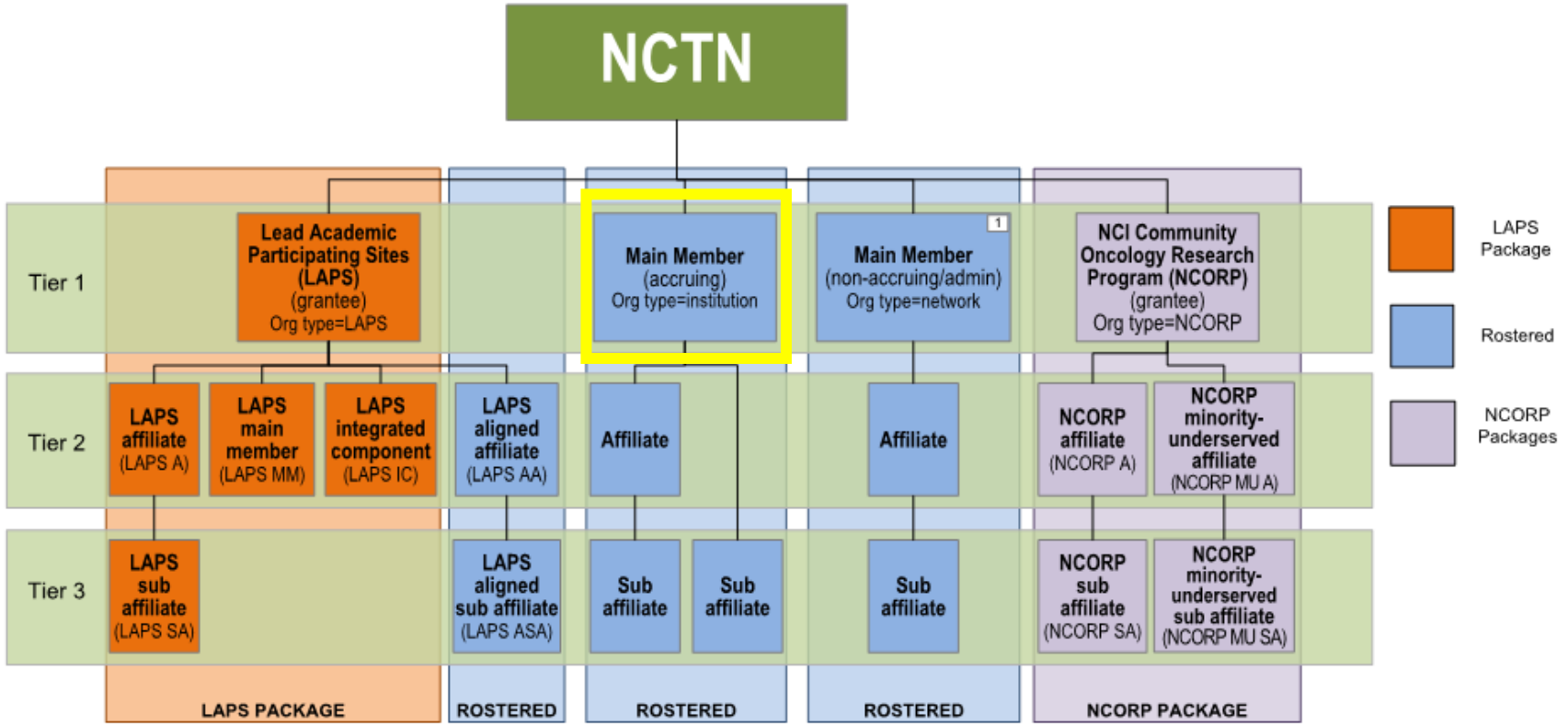
Number of affiliates: 1

Number of active trials: 25

Years Experience: 8

Fun Fact: I pivoted to clinical research from a career in marine biology (yes, seals, dolphins, & whales)

Where is Your Membership Swim Lane?



1. Pre-approved for Main Member (non-accruing / administrative code) required for CTEP.

Rachel Kitchen
Senior Regulatory Affairs Coordinator

Institution Name: UC Davis Comprehensive Cancer Center

SWOG Membership: LAPS main member, affiliate & integrated component

NCI CIRB: 1 signatory institution, 3 relying institutions

Number of affiliates: 4 affiliates within the network

Number of active trials: ~40 active trials

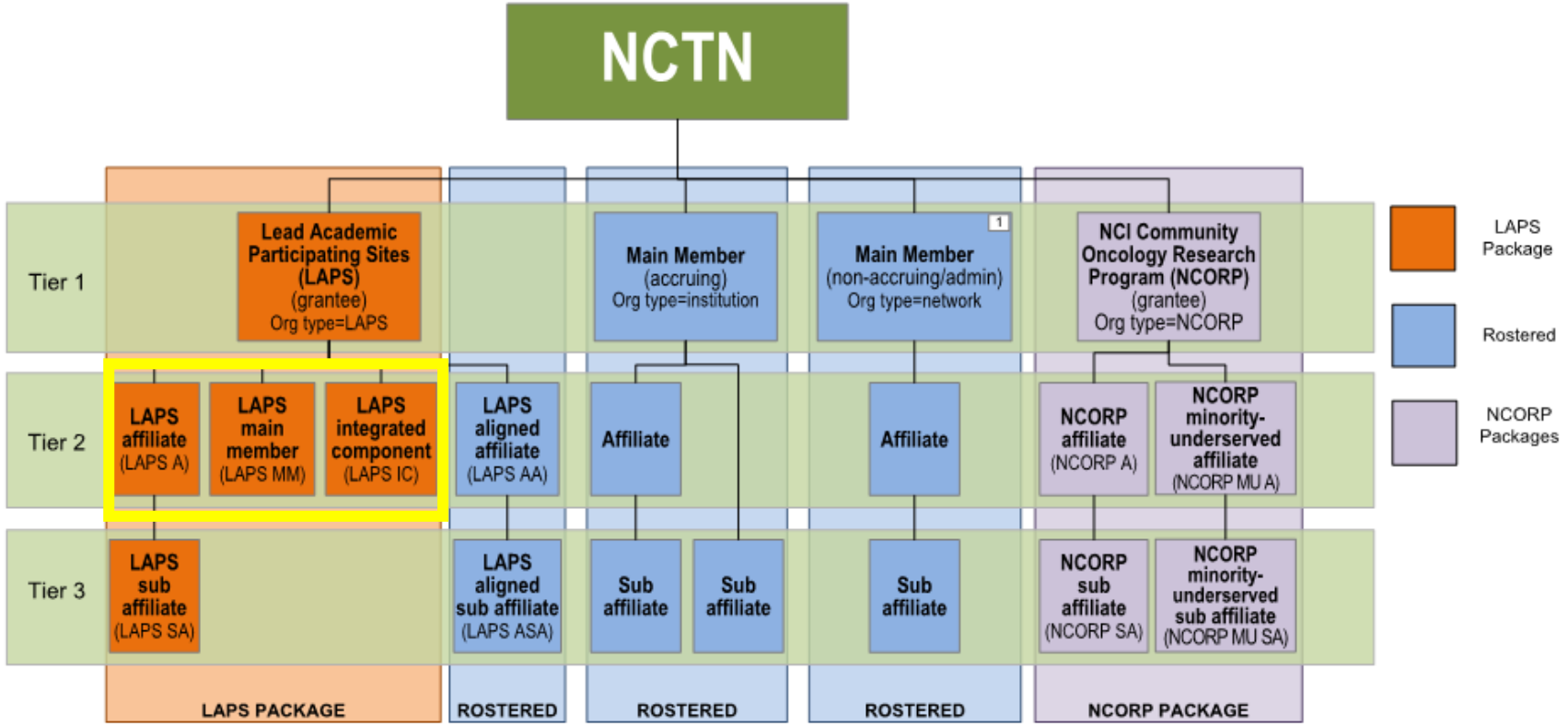
Years Experience: 11 years in cancer research

Fun Fact: I'm a wildlife photographer

UCDAVIS HEALTH | COMPREHENSIVE CANCER CENTER

UCDAVIS HEALTH | UC Davis Cancer Care Network

Where is Your Membership Swim Lane?



1. Pre-approved for Main Member (non-accruing / administrative code) required for CTEP.

Jessica Franzke, BS
Clinical Research Specialist– CROWN Consortium

Institution Name: HSHS St. Vincent Hospital

SWOG Membership: NCORP site – CROWN Consortium

NCI CIRB: 3 unique NCI CIRB signatory institutions within the consortium

Number of affiliates: 29 affiliates across the consortium

Number of active trials: 226

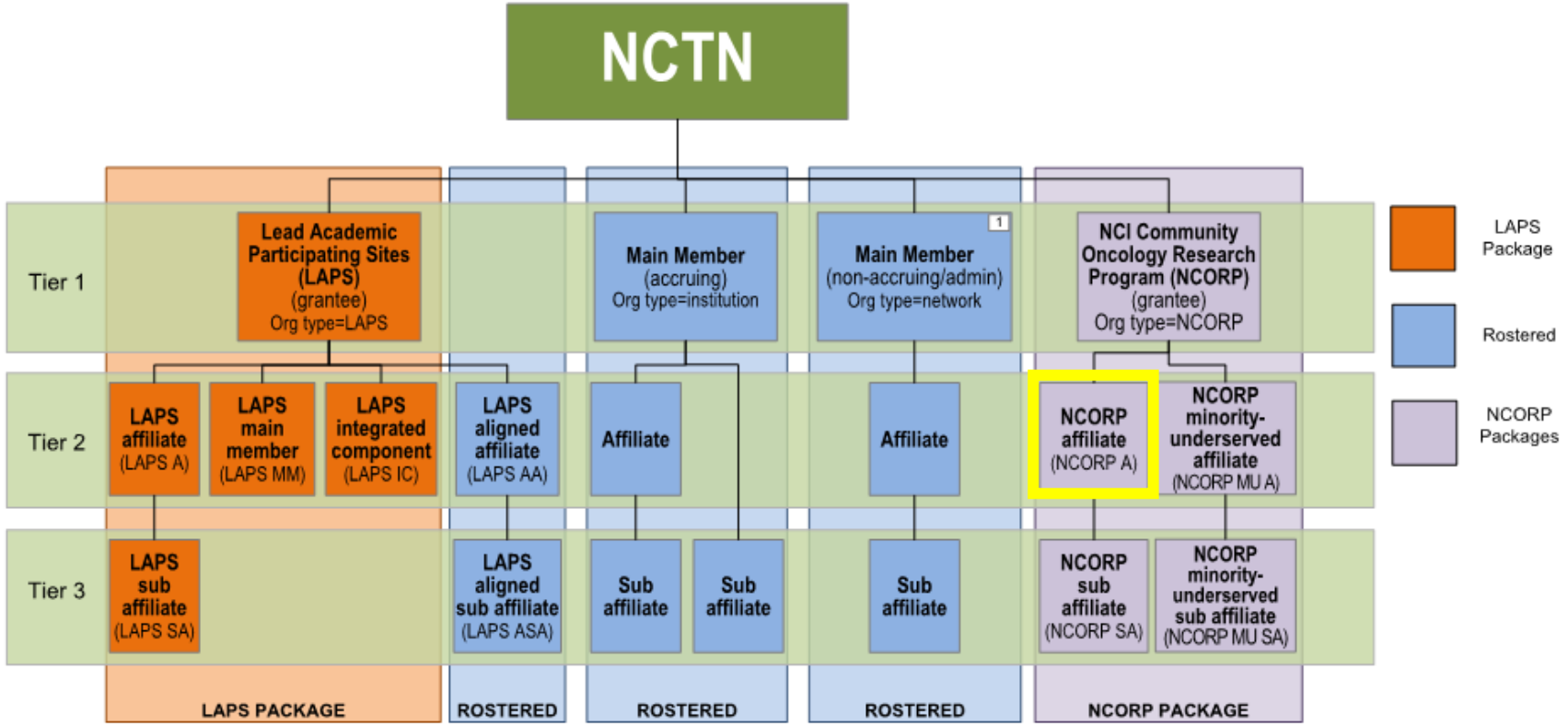
Years Experience: 5 years in cancer research, 2 years in December in regulatory, 4 years with HSHS in January

Fun Fact: I have 4 kids with a total of 12 legs

(2 dogs and 2 kids)

CROWN Cancer Research of Wisconsin and Northern Michigan

Where is Your Membership Swim Lane?



1. Pre-approved for Main Member (non-accruing / administrative code) required for CTEP.

Common Challenges

What is the biggest regulatory challenge you have being a multi-institutional or multi-organizational site?

Common Challenges

Does your site a have specific/detailed guidelines, operations, communications plans, etc. to aide with your multi-institutional challenges?

Common Challenges

What is a one mistake you made and learned from to improve your and your department work? What kind of corrections or prevention actions were beneficial and sustainable?

Why it Matters

Why do you think knowledge about these topics are important for everyone's individual role on the research team?

Closing Remarks

Please join us as we continue the conversation with the Oishi Panelists at the Open Forum *SWOG Perspectives and Common Challenges Breakout Session #4 at 1:15*

Thank you

Oishi Symposium Closing Session: Past Accomplishments, New Directions, and Hope for the Future

With contributions from
the Oishi and Open Forum Presenters

"The only constant in life is change." – Heraclitus

When you are finished changing, you are finished". – Benjamin Franklin

Looking back on Operational Changes

(AKA-Operational Changes [Challenges] we have Mastered!)

- 1999: CTSU: Central registration
- 2001: CIRB chartered
- 2003: Spectrack as a SWOG specimen tracking system
- 2004: Pediatric CIRB
- 2013: OPEN central registration and ETCIRB
- 2016: National Clinical Trials Network (2014) & the Experimental Therapeutics Clinical Trials Network
  - *12 Research Bases → 4 Adult Groups (SWOG, Alliance, NRG, ECOG-ACRIN) + 1 Pediatric Group (COG)
  - *Central trial registration on CTSU across most all trials (not as dependent on the group you 'belong to')
- 2017: CCOPs and Academic Medical Centers became NCORPs, LAPS, Main Members, and High Performing Sites
- 2017: RUMS - CTSU
- 2012: Medidata RAVE
- 2016: NCTN standardized NCAs
- 2022: PMB begins Aurora (2022) & NCI implements ID.me

Timeline of Operational Activities

1936: NCI created by President F. D. Roosevelt

1955: NCI created Cooperative Group structure

LOOK HOW MUCH WE'VE MANAGED AND ADAPTED TO IN THE LAST 40 YEARS!!

1956 SWOG Leading cancer research. Together.

1999: CTSU Created

2001: CIRB Created

2013: OPEN Created

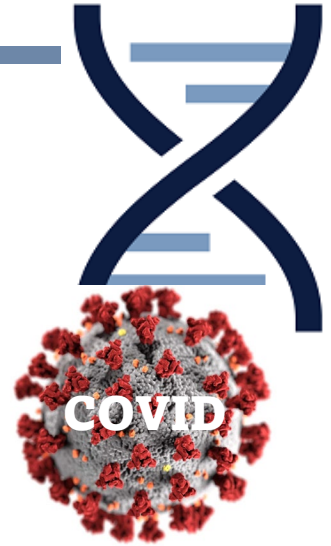
2014: NCI NCTN Created

2016: NCAs for NCTN Trials

2016: ETCTN Created

2017: CTSU RUMS begun

2022: ID.me & PMB Aurora



1930 1940 1950 1960 1970 1980 1990 2000 2010 2020 AND BEYOND!

70 YEARS OF OPERATIONAL MILESTONES SUPPORTING GREAT CANCER RESEARCH

SWOG CANCER RESEARCH NETWORK

NCI National Clinical Trials Network — a National Cancer Institute program

NCI Community Oncology Research Program — A program of the National Cancer Institute of the National Institutes of Health

Successes and Silver Linings

- We survived one of the worst pandemics and lived to “tell the tale”!
- The flexibilities build it the time of COVID, are, in many cases continuing:
  - Remote consent/reconsent
  - Shipping of oral agents
  - Remote monitoring/auditing for trials
- CTEP policy changed for APPs, who are now allowed to be CTEP Sub-Investigators and practice to the full extent of their license.

NCI and ID.me Implementation

Fall 2022 NCTN Group Meetings

NIH NATIONAL CANCER INSTITUTE

Fall 2022

ID Verification for NCI Systems

- Identity verification and multifactor authentication (MFA) is required for all federal systems and meets NIST SP 800-63-3 Digital Identity Guidelines
  - This is a **Federal** (not NCI) requirement for all **Government** IT applications. Failure to comply will result in a system shutdown
- Beginning July 8, 2022, CTEP-IAM integrated with ID.me to meet this requirement
- All users must complete ID verification and multi-factor authentication (MFA) with ID.me by July 1, 2023

Making sure all users are whom they say they are

What is ID.me ?

- ID.me has been leveraged by federal agencies, states, and private companies in providing a secure digital identity network
- ID.me provides the strongest identity verification system available to prevent fraud and user identity theft
- This service uses bank-grade encryption to keep your personal information safe
- ID.me's primary goal is to ensure sufficient evidence of a user's identity in order to meet NIST SP 800-63-3 Digital Identity Guidelines

ID.me Privacy Bill of Rights

You solely control your own data

You control the data you provide during the verification process

You must provide explicit consent before ID.me will share any information

You can revoke access to your data for any authorized app at any time

You can destroy your ID.me credential and associated data at any time

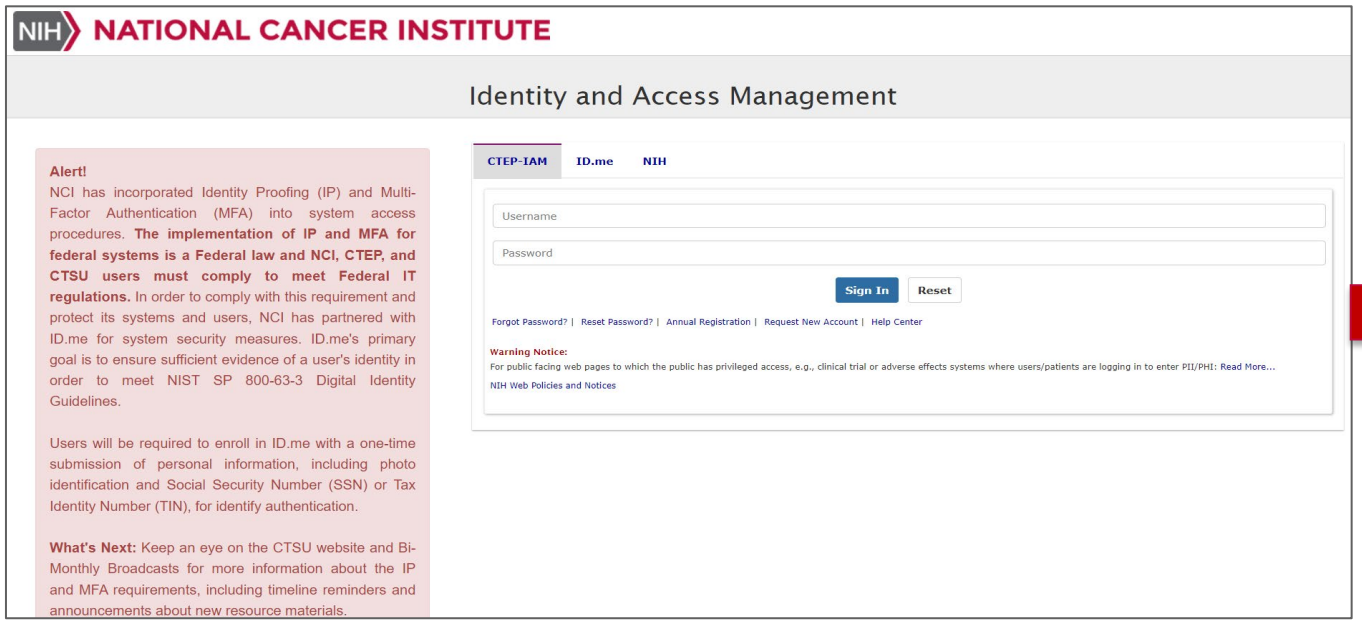
Refer to the Privacy Bill of Rights on ID.me

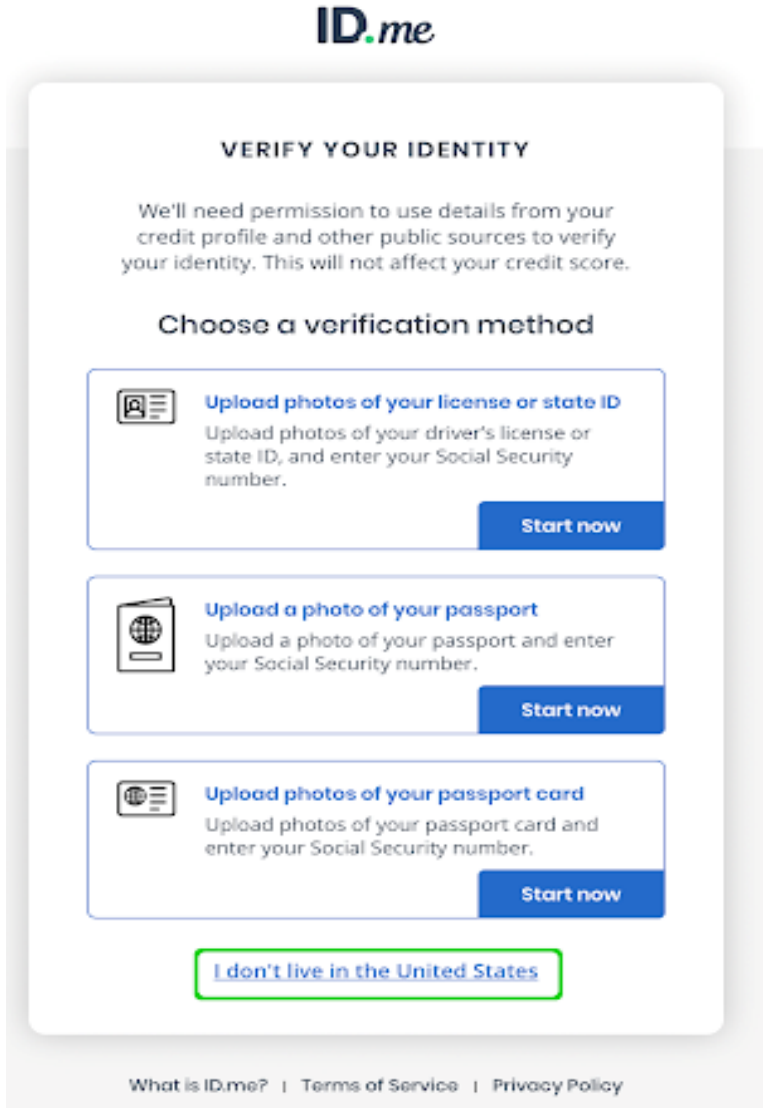
Privacy Bill of Rights: https://insights.id.me/privacy-bill-of-rights/

Why ID Verification?

- Identity verification allows ID.me to ensure that a user's claimed identity matches their actual identity
- MFA uses something you know and something you have for second layer of account security
- Did you know: MFA prevents 99.9% of identity attacks

CTEP-IAM ID Verification and MFA Set-up





- Users will go directly through the CTEP- IAM application for ID verification and MFA set up
- Existing users will log in to CTEP-IAM
- New users needing CTEP-IAM access will request a new account.
- After logging in or requesting new account, users will follow instructions to verify identity and set up MFA through ID.me

ID.me- *What You Need to Have:*

1 unique identifier: U.S. Social Security Number (SSN), U.S. Individual Tax Identification Number (ITIN), or valid passport number (*only option for users that live outside of the US*)

2-3 identification documents: Driver's License, State I.D., Passport, etc. Go to the ID.me page to see which documents are accepted for U.S. users and those who do not live in the U.S.

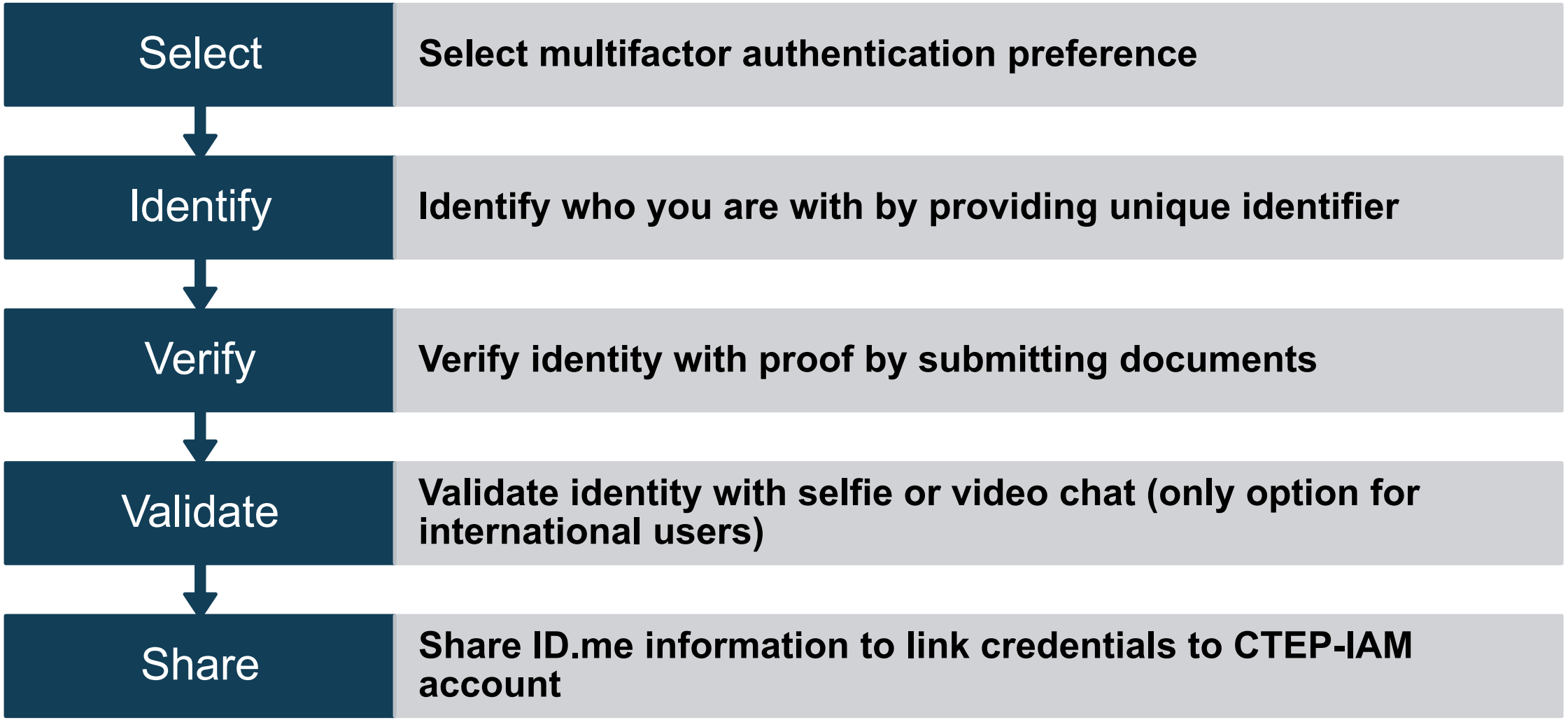
Identity verification device: A smart phone or computer with front facing camera

Multi-factor authentication device: Text message service, phone (mobile or landline), or authenticator app

Note: The first three identity requirements are only needed ONCE for the **one-time** ID verification process.

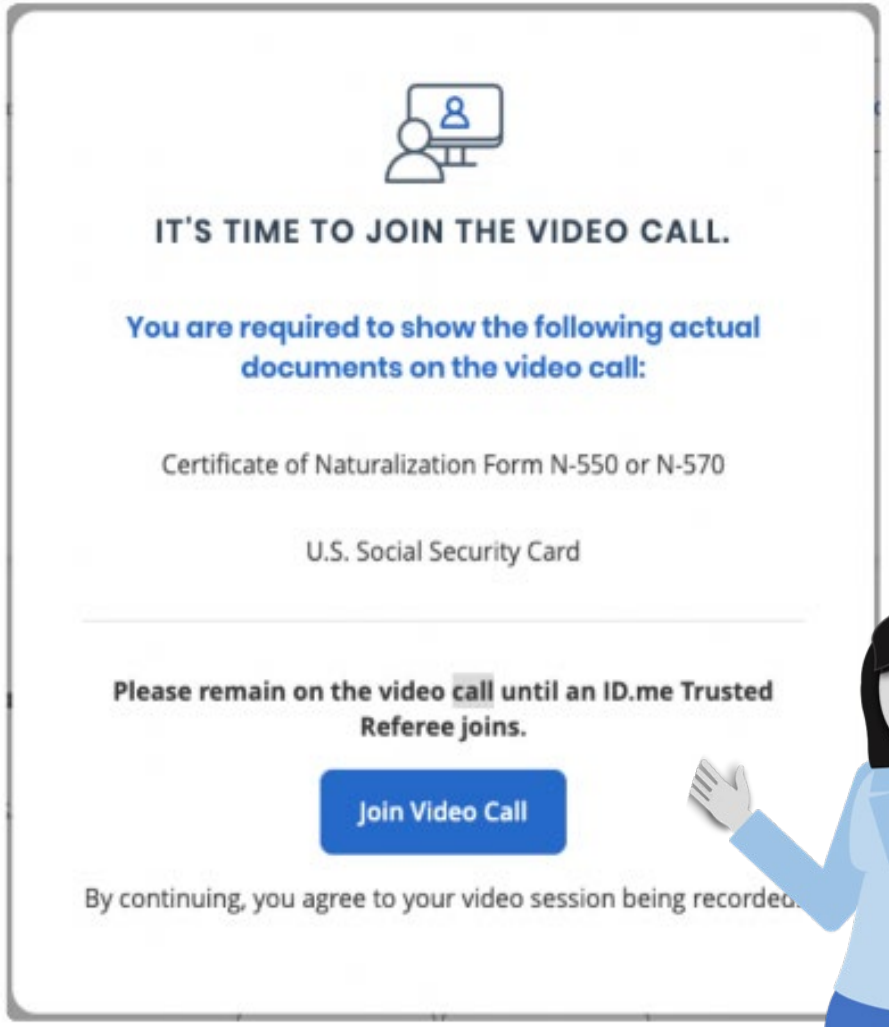
MFA is used **each time** upon sign-in.

ID.me- *What You Will Need To Do:*



Trusted Referee

- Users who live outside of the U.S. **must** validate identity through an ID.me video chat agent, known as a Trusted Referee
- Users who live in the United States have the option to validate identity with a Trusted Referee, and may see this option if their first online identity verification attempt was unsuccessful
- **Please note: validating identity with a video call, still requires users to upload required identification documents**
- After joining video call and showing the Trusted Referee your documents, your one-time identity verification process will be completed
- Your wait time for a Trusted Referee may vary, but you can choose to return later at a time that works best for you



Helpful Resources and Tips

- Users who live in the U.S. have the option to submit SSN or ITIN for unique identifier requirement. Users who have never been issued such identifiers or who do not live in the U.S. must submit a valid passport number for this requirement
- Users who do not have a valid passport or other required documents will be allowed to temporarily bypass the ID.me process and continue using their CTEP-IAM accounts up until July 2023
- For further assistance with this matter and all other questions regarding this process, please contact ctephelpdesk@nih.gov
- Check out NCI & ID.me for more info about this integration
- Contact ID.me support for assistance with your ID.me account
- Visit the CTEP website for detailed instructions, FAQs, and other helpful information
- Additional communication will be provided on upcoming webinars and live trainings

The Future – it is Now!

- Use of e-Reg or electronic regulatory platform/system
  - Different vendors currently: e-Reg (Advarra), Complion, Florence, Veeva, “home-grown” systems
  - Can allow shared documents, remote auditing, Part 11 compliant, electronically routed document signatures, paperless systems
  - $$$$
- SIPs: Shared Investigator Platforms
  - Predominantly used in industry
  - Different providers: Cognizant,
  - External portal to distribute, exchange, and house study documents
  - Labor intensive system to set up/maintain

nCartes

Key Points:

- Project of nCoup (corporation) in partnership with SWOG and Medidata RAVE; form of direct data connect
- Current phase of testing: Pilot at 3 sites in the SWOG network
- Decreased coordinator time entering structured data (i.e. labs)
- Decreased coordinator time clearing transcription errors/responding to queries

Institutional Medical Record → Site integration →  → Push from nCartes → SWOG Rave Database

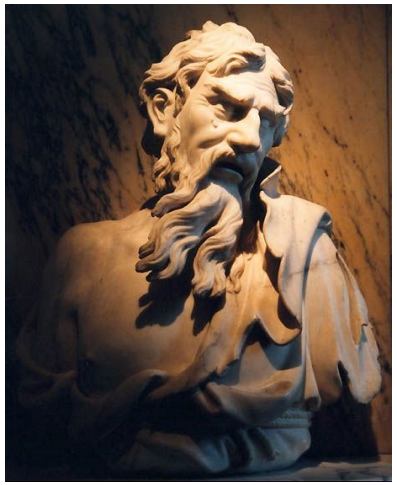
EMR Template & Guide

- The concept of sharing standard work is not a new one.
- The special initiative grew out of the work done previously by the NCI, the Groups, and a host of partners/collaborators for National Coverage Analyses which are now in use across the NCTN Network.
- The initial work is agnostic to EMR system and utilizes a templated Excel worksheet which is the “roadmap” for an EMR order sets.
- Currently two NCTN groups of trials are the focus: ComboMATCH & MyeloMATCH
- As updates become available, they will be shared.
- Feedback offered to the NCTN Groups indicating interest would be helpful.
- More at https://www.ctsu.org/master/simplepage.aspx?ckey=EMR-TEMPLATE-GUIDE

Efforts on Broadening Eligibility

In an age when therapy is molecularly tailored/targeted and eligibility has narrowed, the NCI is acutely aware of this impact on enrollment in clinical trials.

- CTEP conducting a pilot project reviewing new NCTN protocol documents with a focus on eligibility criteria. [1]*Denicoff AM et al, JNCI 2022, PMID: 36047830*
- The prospective review asks Investigators to review and justify restrictive protocol eligibility criteria. Recommendations are also included.
- The comparison is based on the NCI eligibility template adapted from the ASCO-Friends guidance, so there is standardization on protocol design & comparison. [2]*Kim ES et al, Clin Cancer Res 2021, PMID: 33563632*
- In initial review, majority of changes recommended were accepted and broadened eligibility.
- NCI Eligibility Criteria Template and Guidance: https://ctep.cancer.gov/protocolDevelopment/docs/CTEP_Broadened_Eligibility_Criteria_Guidance.pdf



The ancient philosopher Heraclitus of Ephesus (530-470 BC) is one of the most important thinkers in history. Heraclitus' philosophy is a good starting point for anyone concerned with change in life. Heraclitus said that life is like a river. The peaks and troughs, pits and swirls, are all are part of the ride. Do as Heraclitus would – go with the flow. Enjoy the ride, as wild as it may be. Heraclitus was born into a wealthy family, but he renounced his fortune and went to live in the mountains. There, Heraclitus had plenty of opportunity to reflect on the natural world. He observed that nature is in a state of constant flux. 'Cold things grow hot, the hot cools, the wet dries, the parched moistens', Heraclitus noted. Everything is constantly shifting, changing, and becoming something other to what it was before. Heraclitus concluded that nature is change. Like a river, nature flows ever onwards. Even the nature of the flow changes.

Heraclitus, change, and flow – Philosophy for change (wordpress.com)

Some conclusions:

- As Oncology Research Professionals, you have operationalized a great many initiatives; keep the first slides of this presentation uppermost in your mind as you face a future with more change. Always remember this and be proud.
- As Oncology Research Professionals we have made a difference in people's lives. Always remember this and be proud.
- Many owe their careers to the support and actions we do every day. Always remember this and be proud.
- Each of us has an obligation to pass the 'legacy' of our work to a new group, sharing skills, teaching process, coaching actions, and supporting each other. Always remember this and be proud.
- And when someone you work with has a 'bad day' (which we all have from time to time), remind them of all we do for the research enterprise. Always remember this and be proud.