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Implementation of an Electronic Regulatory Binder System at CHLA

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Office of Regulatory Affairs
Human Subjects Protection Program

Why are Regulatory Documents Required for Clinical Trials?

- Regulatory documents are submitted to track and evaluate the ethical and procedural conduct of a trial and the quality of the data that is produced
- Regulatory documents demonstrate the compliance of the Investigator, Sponsor and IRB with the standards of Good Clinical Practice and with all applicable regulatory requirements
- Please note:

Requirements depend on types of studies, sponsors, IRB of record, etc.

Good Clinical Practice (GCP)

- "Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects." ~1996

- ICH GCP E6, section 8 - Essential Documents for the Conduct of a Clinical Trial - "8.1 Essential Documents are those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced."

Requirements can be found here:

- ICH-The International Council for Harmonisation
- www.ich.org
- CFR-Code of Federal Regulations HHS
- www.fda.gov
- Department of Health and Human Services
- http://ohrp.osophs.dhhs.gov
- CHLA:

Human Subjects Protection Program (HSPP) and Institutional Review Board (IRB)

- External IRB of Record

What Kind of Documents are Required ?

Depending on the nature of the research, some sections may or may not be required. Use this list to ensure that the applicable sections are maintained.

1. HUMAN RESEARCH
   - a) Protocol
   - b) Institutional Review Board
   - c) Consent
   - d) Data Collection
   - e) NIH
   - f) Sponsor
   - g) Data Safety Monitoring Board/Data Monitoring Committee
   - h) Training Records
   - i) External IRB Documentation
   - j) Ethics Committee/Community Advisory Board

DOCUMENTATION

   - k) Scientific Review
   - l) Data Protection
   - m) Other

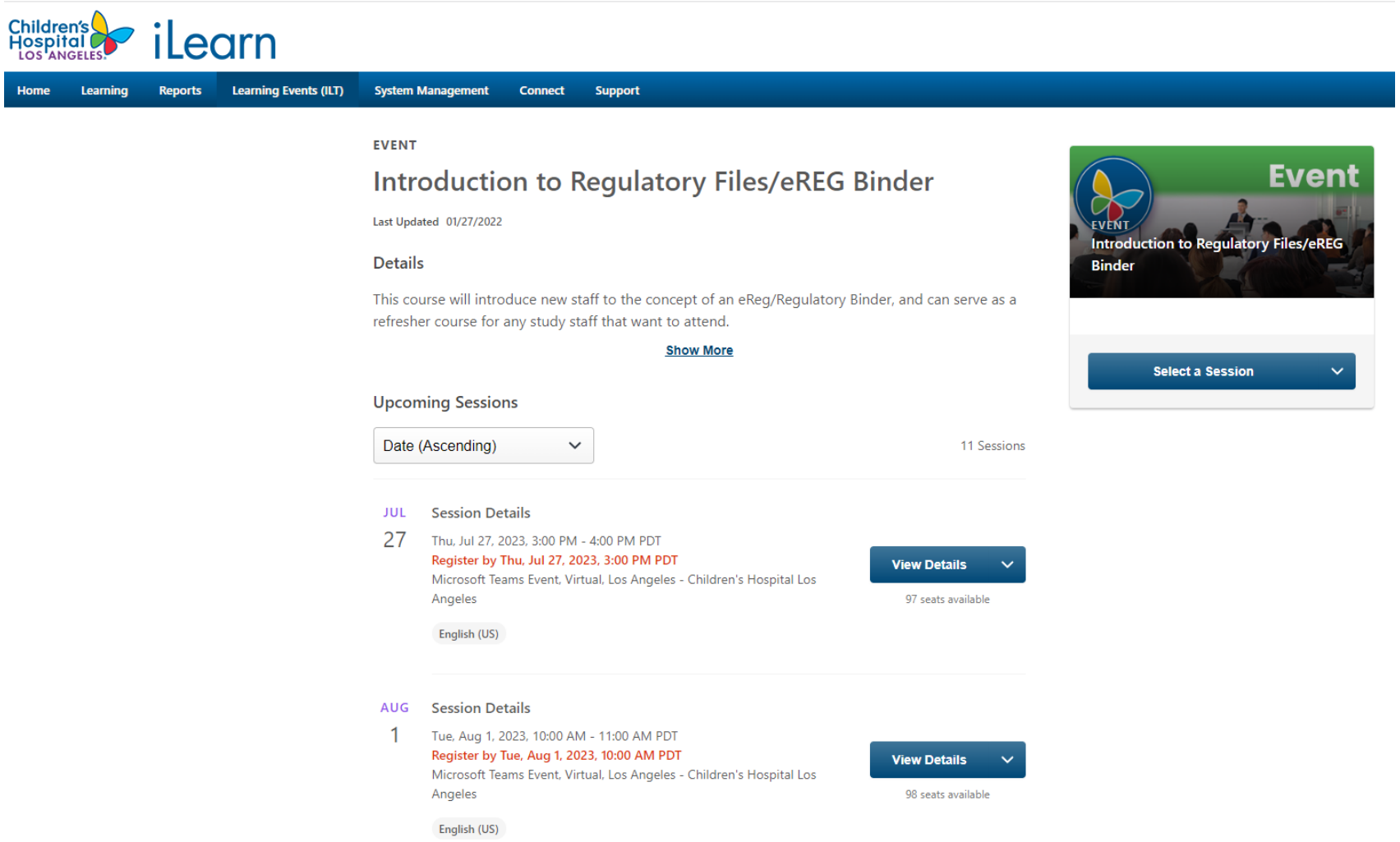
Specific Regulatory Requirements

This session does not detail all required regulatory documents.

That information is presented twice a month via iLearn.

The CHLA research community is welcome and encouraged to complete that training ☺

Introduction to Regulatory Files



Regulatory Documentation

A methodical and well-executed system to manage regulatory documents is critical for efficient project management and regulatory compliance.

All required elements should be present and *easy* to produce

“If it isn’t documented, it didn’t happen.”

ICH GCP E6, section 8

Standard Regulatory Binders

Regulatory Records at CHLA

Currently CHLA does not have ONE consistent way to maintain regulatory documents.

Teams use:

- Physical binders
- eReg-via share drive
- Hybrid-eReg AND paper documents for wet signatures
- SharePoint
- Teams

Benefits of Using an eReg System

- Reduce redundancy in document management
- Reflect dynamic nature of a clinical trial
- Facilitate document monitoring
- Facilitate staff/study transitions
- Efficient regulatory start up
- Convenient access to your research team
- Reduce paper budget
- Increase desk and overhead space
- Reduce time printing and coping documents
- Reduce time updating documents (CVs, licenses, GCP certificates etc.)*
- Streamline study start up activities

Benefits of Part 11 Compliant eReg

What does Part 11 compliance mean?

This is specific to the validity of electronic signatures for *federally funded* research

This refers to the Code of Federal Regulations:

Electronic Records; **Electronic Signatures** (21 CFR Part 11)

- Electronic signatures-are intended to be the equivalent of handwritten signatures, initials, and other general signings required by predicate rules. Part 11 signatures include electronic signatures that are used, for example, to document the fact that certain events or actions occurred in accordance with the predicate rule (e.g. approved, reviewed, and verified).

If your study is NOT FDA regulated, you may be able to use DocuSign. Consult your sponsor and/or IRB of Record.

Electronic Signatures

If your study is **NOT FDA regulated**, you may be able to use a NON-Part11 eSignature platform like:

DocuSign, RedCap, or Adobe Acrobat.

Consult your sponsor and/or IRB of Record

If you need a Part11 version of Docusign you can purchase one from IT/IS.

Electronic Signatures

Many essential documents must be signed, including:

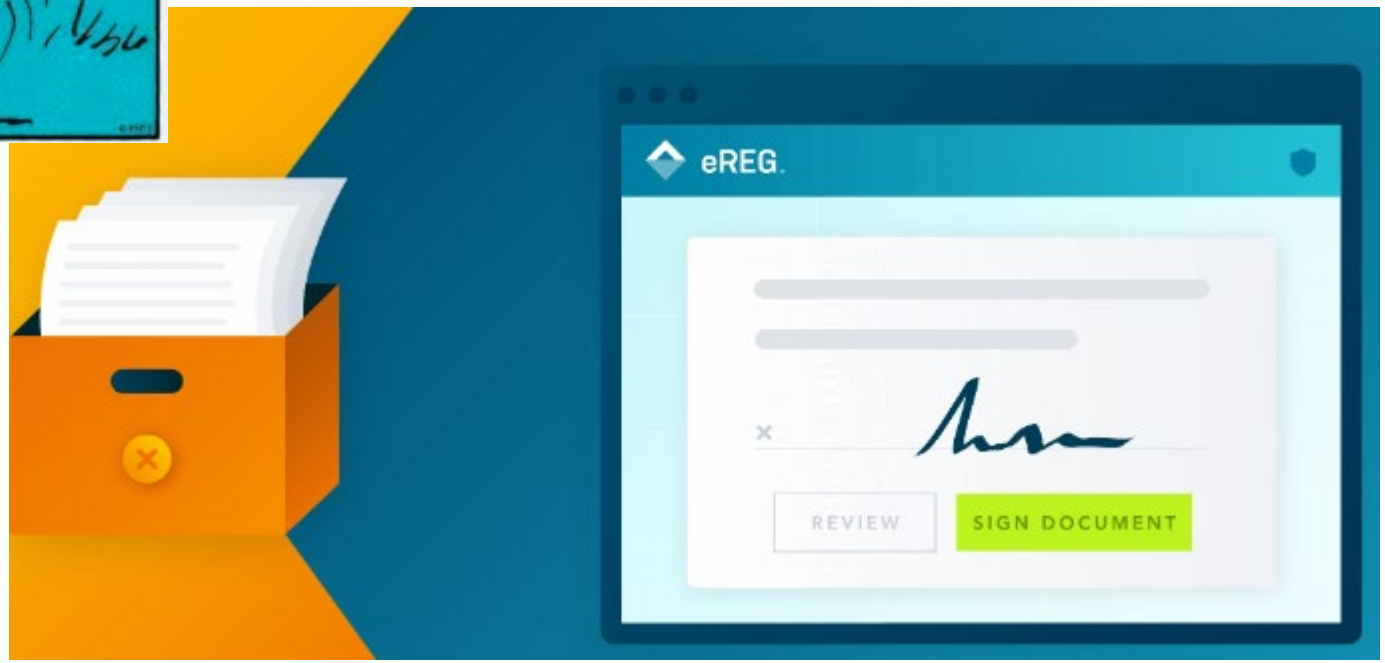
- Protocol Signature Page
- Investigator Brochure Signature Page
- **Delegation of Authority (DOA)***
- FDA Form 1572
- Training Logs
- Financial Disclosure Forms

Efficiency

- Obtaining signatures from multiple staff, at multiple locations and at multiple times is extremely time consuming. Especially now with staff who have both, an on site and remote working environment.

- Teams have multiple studies, going through this process at any time for any study, is not an efficient use of everyone's time

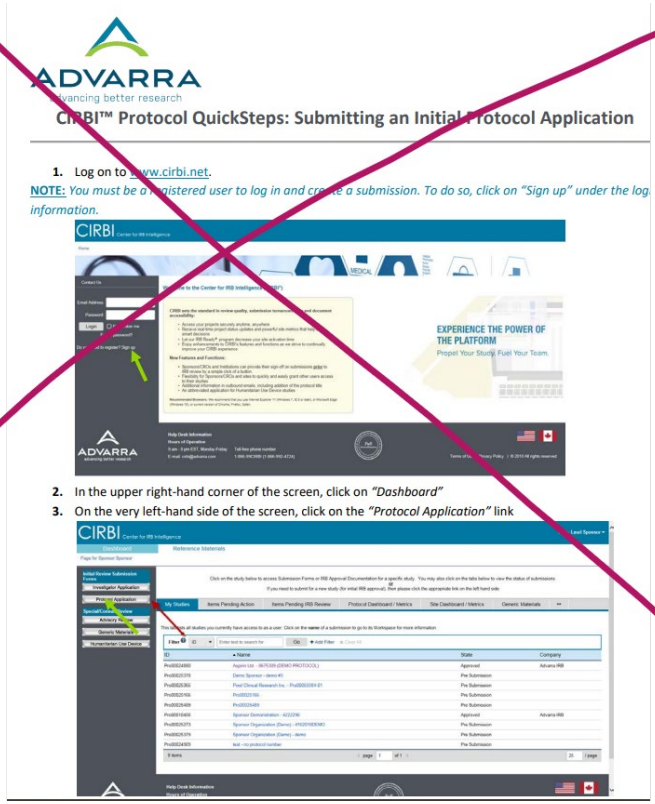
CHLA NOW HAS A PART 11 COMPLIANT EREG SYSTEM!!!



CHLA is implementing use of the Advarra eReg platform

ANYONE CAN USE Advarra eReg
It does NOT have to be a study using the Advarra IRB (CIRBI) as the IRB of Record

Advarra eReg Platform
NOT CIRBI, Advarra's IRB Platform



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Benefits of eRegulatory

ORGAINZED RECORD MANAGEMENT

Many groups want to ensure compliance and safety.

1. Your Investigators-Internal QA
2. Our Quality Assurance/Quality Improvment Program Manager-CHLA quality review
3. The Study Sponsor-Interim Monitoring Visits
4. Coordinating Centers-Audits and/or monitoring visits
5. U.S. Food and Drug Administration-Audits

Benefits of eRegulatory

REMOTE MONITORING

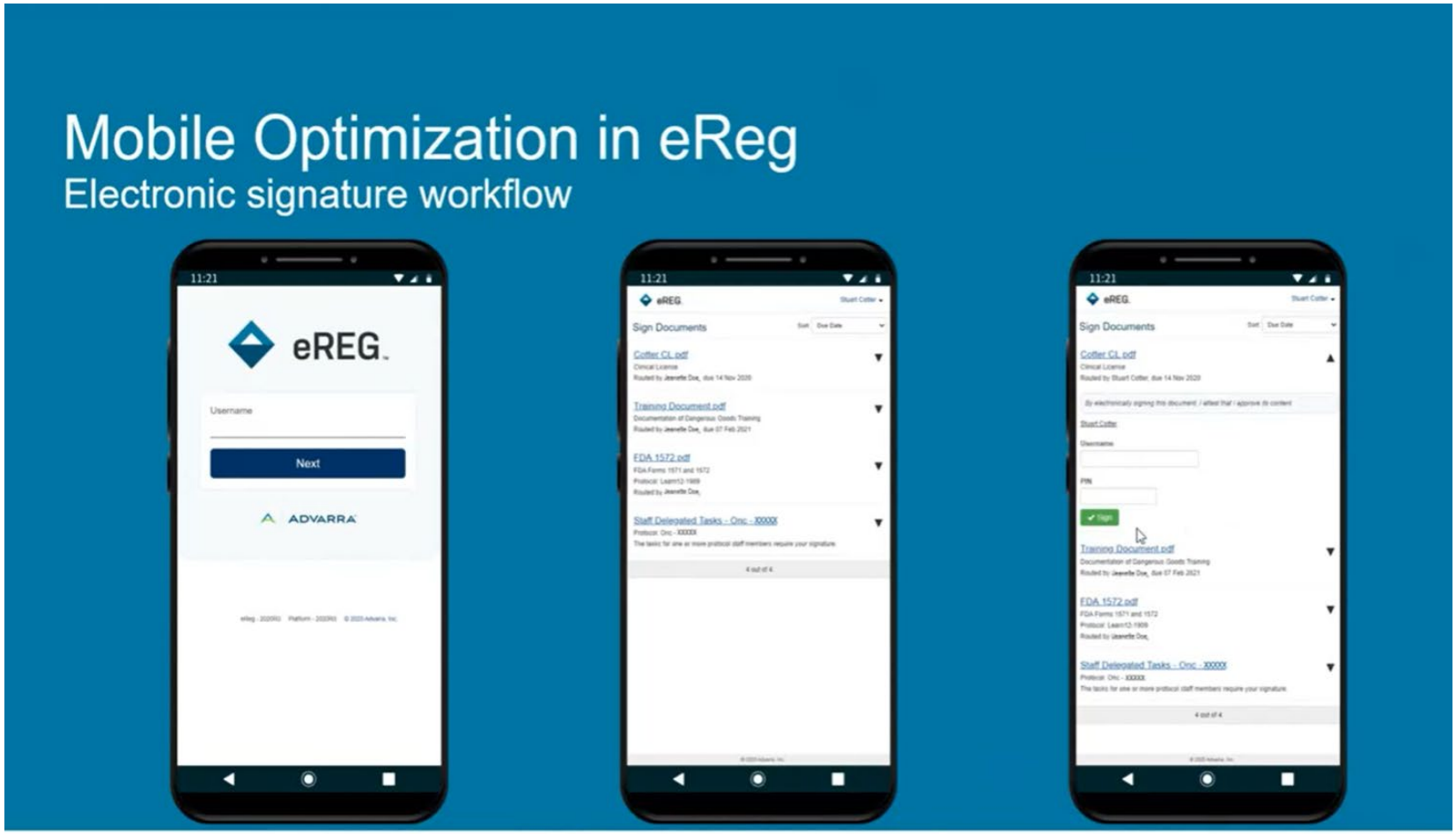
Does eReg support remote monitoring?

Yes. The eReg system allows regulatory staff to generate a unique monitoring user and login, indicate the specific protocol document and information to be reviewed, and control the start and stop points for the monitoring session.

Benefits of eRegulatory

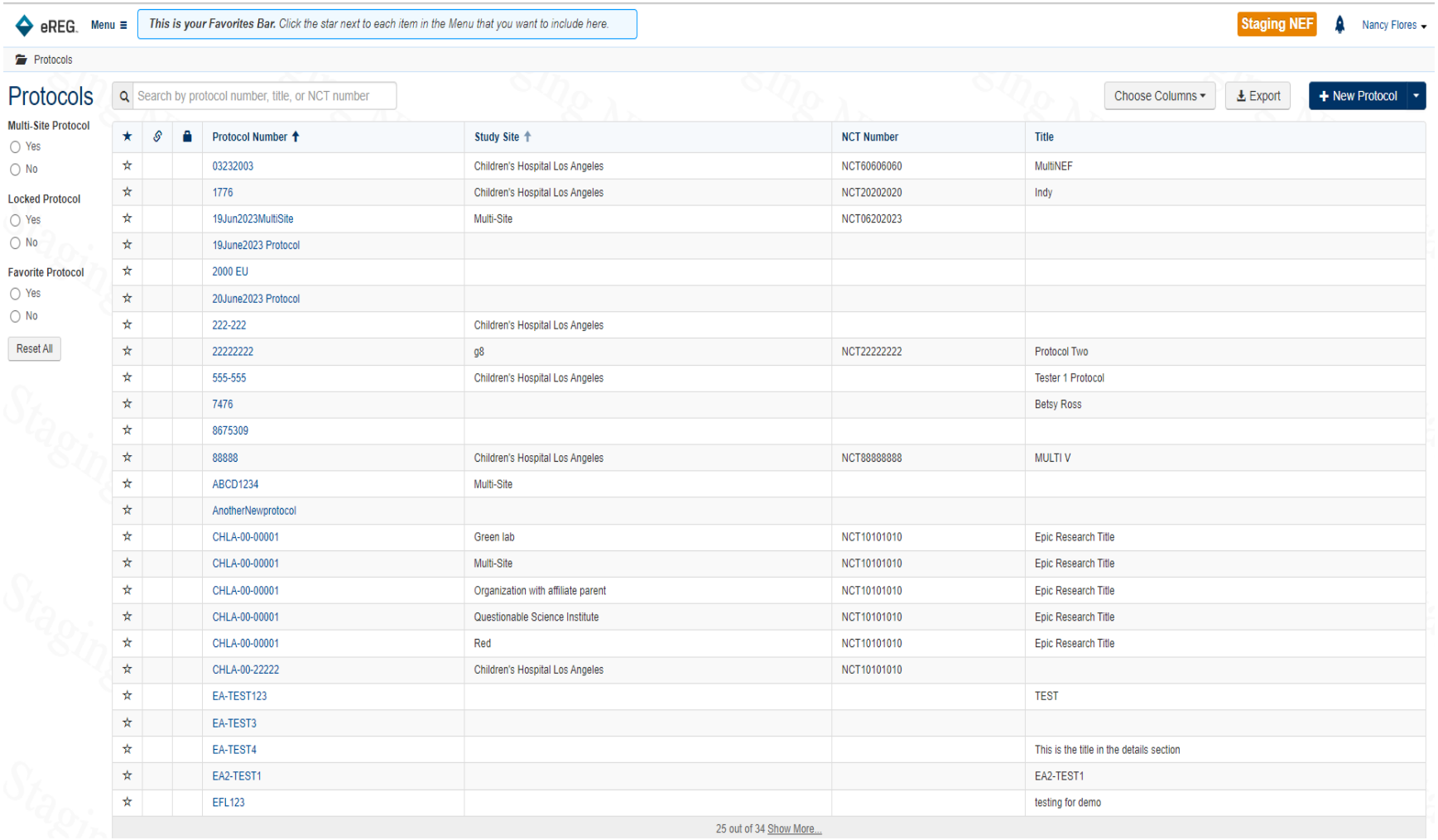
MOBILE electronic signatures

Another Benefit of EREG



ADVARRA

What does an eREG look like?



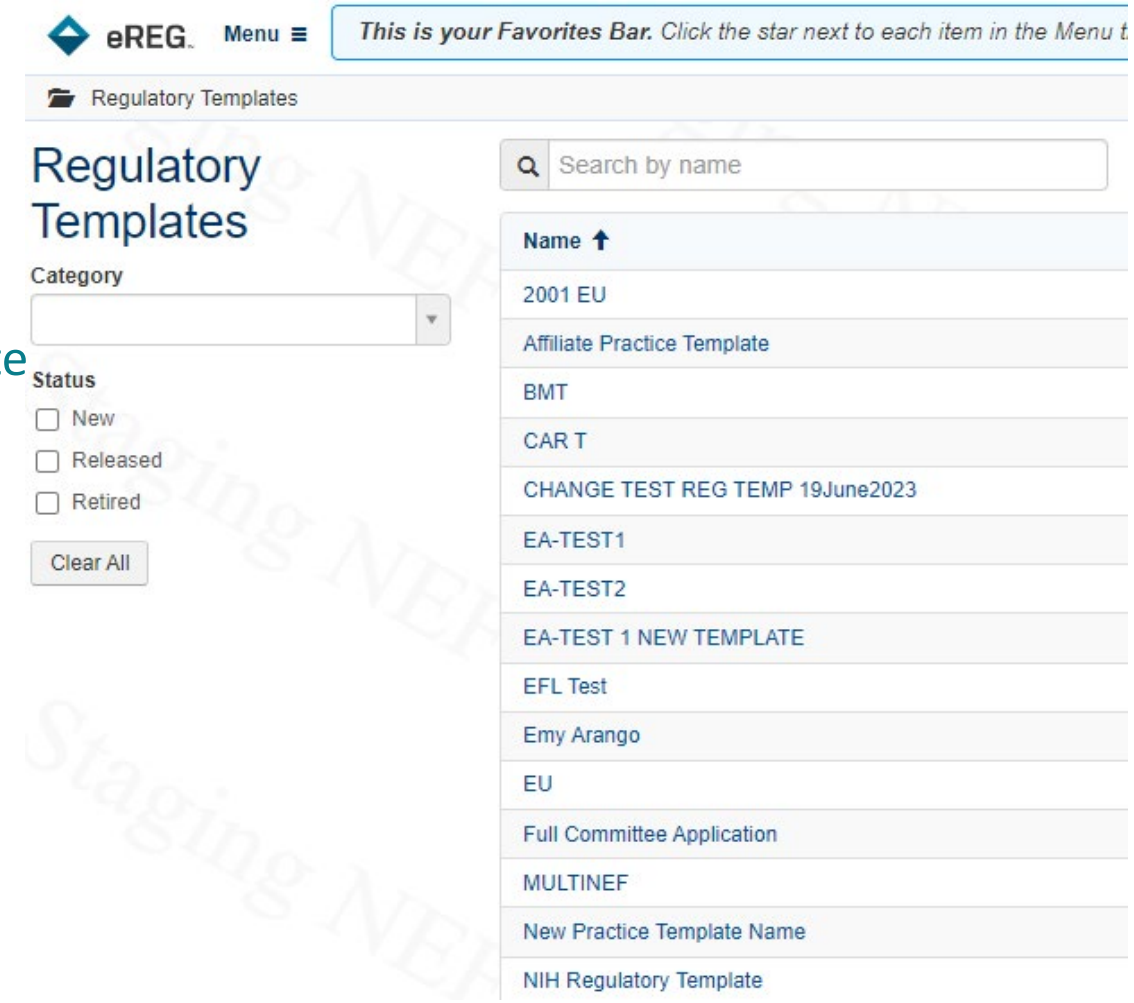
Regulatory Templates-tailor to your needs

TYPES OF TEMPLATES:

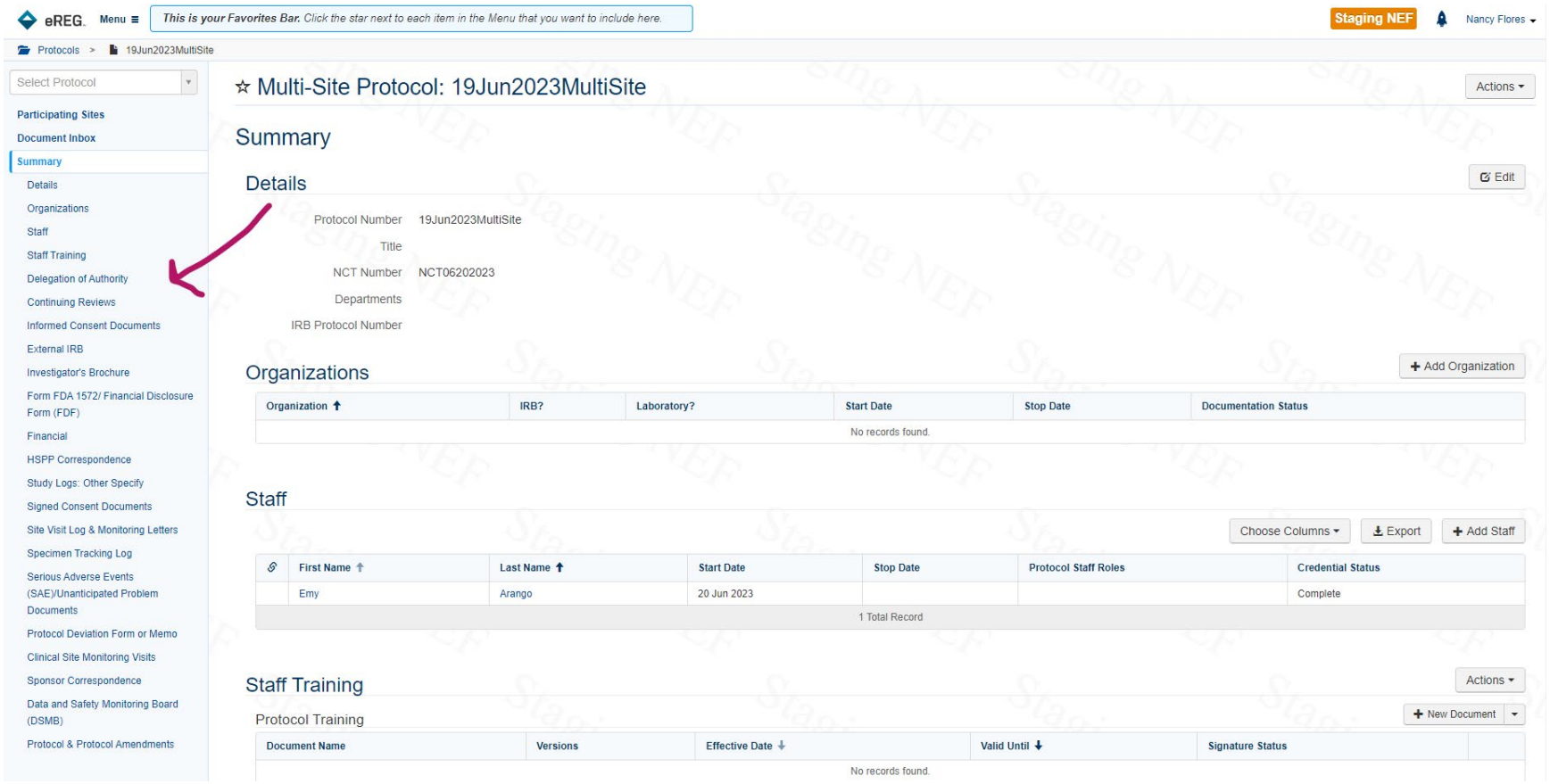
NIH Template

Multi Site Template

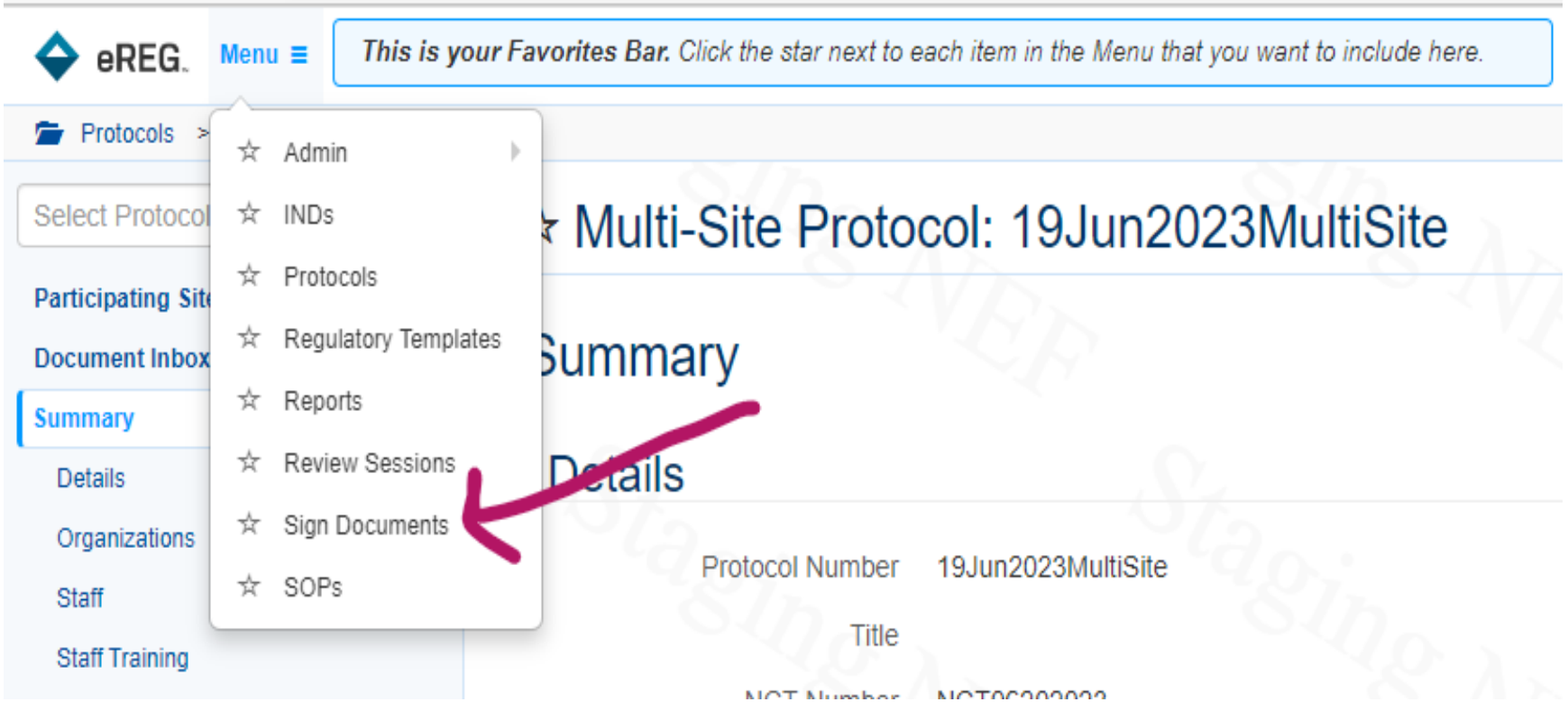
Investigator Initiated Template



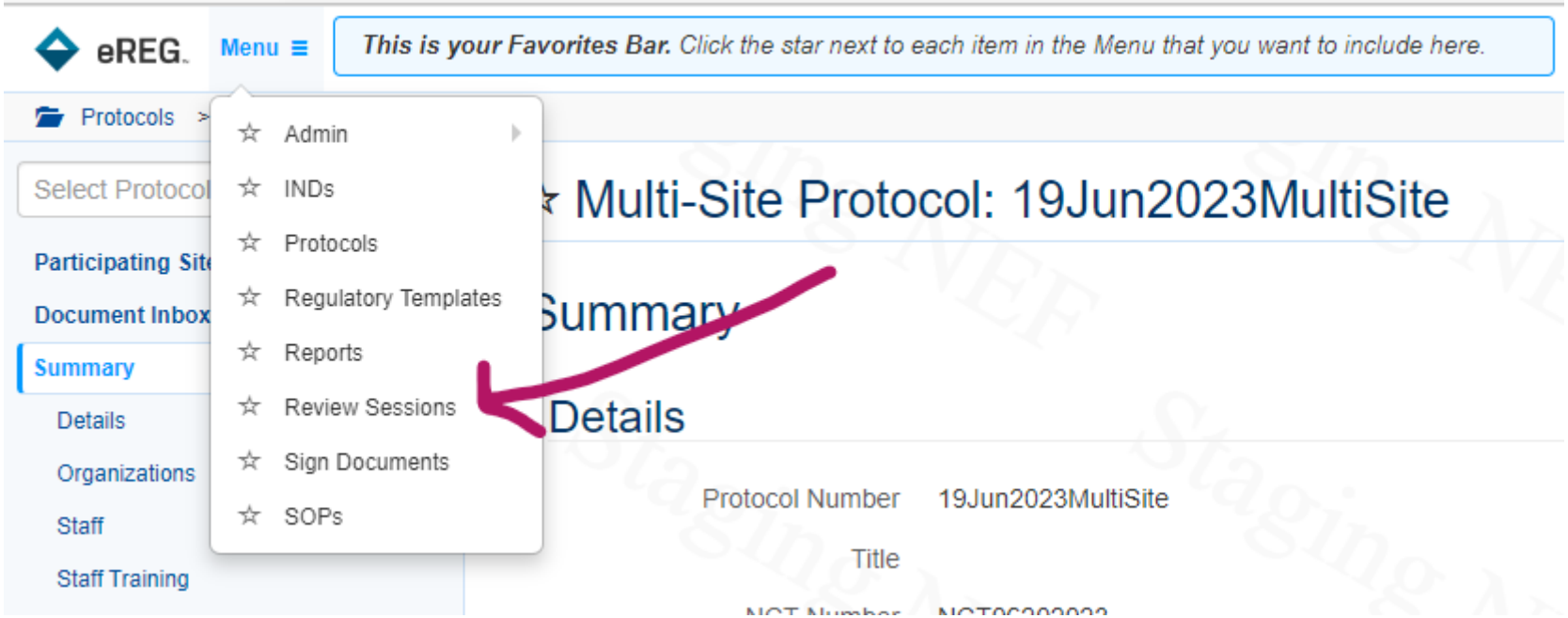
Protocols


eREG.
Menu
This is your Favorites Bar. Click the star next to each item in the Menu that you want to include here.
Staging NEF
Nancy Flores
Protocols > 19Jun2023MultiSite
Select Protocol
Participating Sites
Document Inbox
Summary
Details
Organizations
Staff
Staff Training
Delegation of Authority
Continuing Reviews
Informed Consent Documents
External IRB
Investigator's Brochure
Form FDA 1572/ Financial Disclosure Form (FDF)
Financial
HSPP Correspondence
Study Logs: Other Specify
Signed Consent Documents
Site Visit Log & Monitoring Letters
Specimen Tracking Log
Serious Adverse Events (SAE)/Unanticipated Problem Documents
Protocol Deviation Form or Memo
Clinical Site Monitoring Visits
Sponsor Correspondence
Data and Safety Monitoring Board (DSMB)
Protocol & Protocol Amendments
☆ Multi-Site Protocol: 19Jun2023MultiSite
Actions
Summary
Details
Edit
Protocol Number 19Jun2023MultiSite
Title
NCT Number NCT06202023
Departments
IRB Protocol Number
Organizations
+ Add Organization
Organization
IRB?
Laboratory?
Start Date
Stop Date
Documentation Status
No records found.
Staff
Choose Columns
Export
+ Add Staff
First Name
Last Name
Start Date
Stop Date
Protocol Staff Roles
Credential Status
Emy
Arango
20 Jun 2023
Complete
1 Total Record
Staff Training
Actions
Protocol Training
+ New Document
Document Name
Versions
Effective Date
Valid Until
Signature Status
No records found.

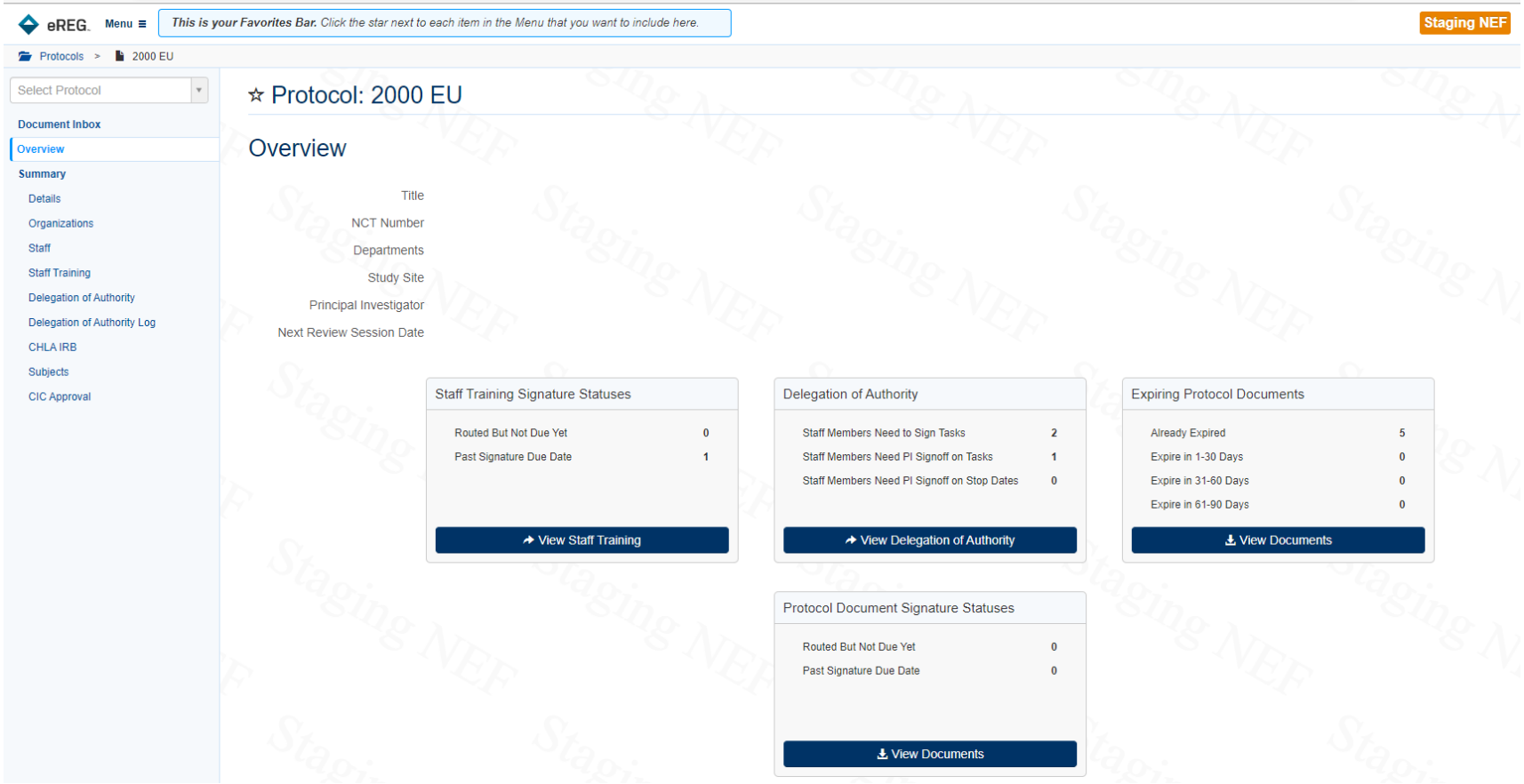
Electronic Signatures



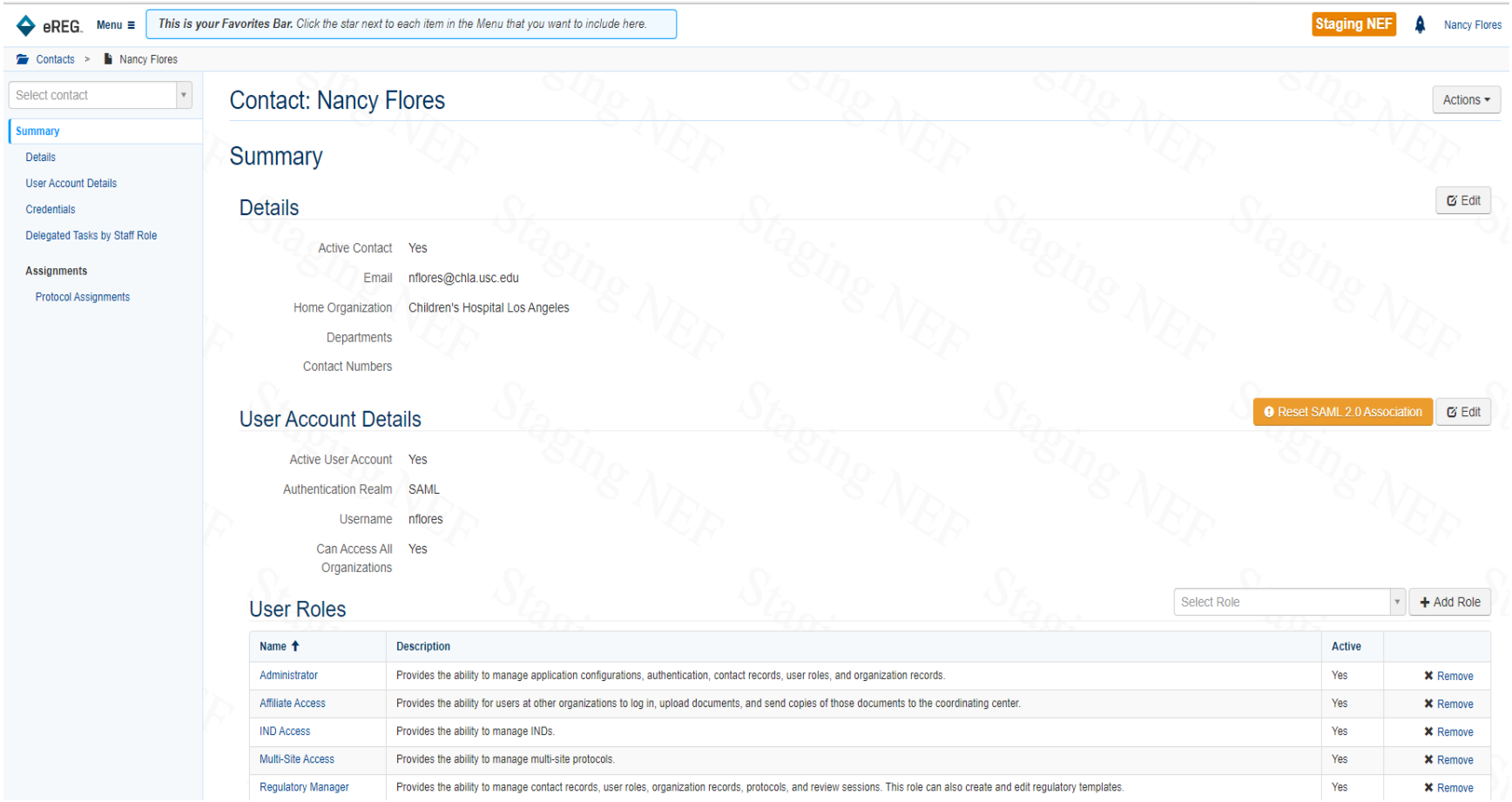
Remote Monitoring



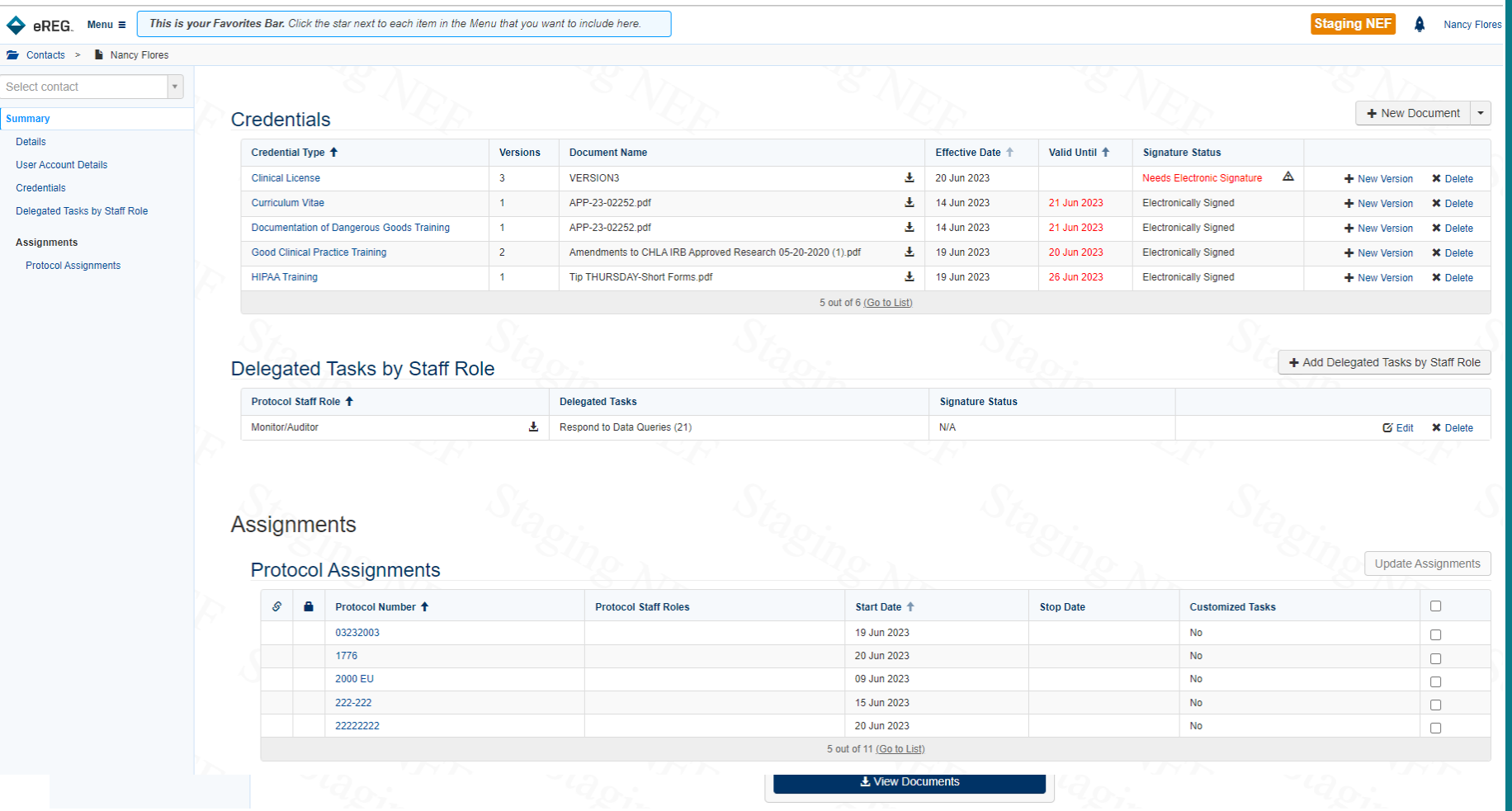
Regulatory Overview



Study Personnel



Team Training & Portfolio



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Yes, please!

Steps to Access & Implement Advarra eReg

- Submit your team information to: ereghelp@chla.usc.edu
- We will provide Advarra University & Training platform access
- Once training is complete and your request form is approved, you will be given account
- Our regulatory specialists will help you with the build/migration of your regulatory documents

Communicate with your sponsor

Ask your sponsor if they are already using Advarra eREG

IF YES:

- The lead or coordinating site that maintains the trial master file in eREG, can transfer those documents to us.
- The process to be added as a site will be much more streamlined

IF NO:

- Confirm that it is acceptable for us to use it for their study
- Ask the sponsor if we use the eReg platform, will they do their remote monitoring using the platform

Communicate with your sponsor

Ask your sponsor/lead-coordinating center if they are already using Advarra eREG

- They maintain the Trial Master File in their Advarra eREG, and can connect to our site and share documents.
- If they are the IRB of Record, this will also streamline document sharing.

Be sure to tell your Sponsor/CRO that they can do remote monitoring now, as we can grant temporary access to our eREG to third parties! (No PHI)

Who is currently using eReg?

Avera McKennan d/b/a Avera Research Institute-Barbara Ann Karmanos Cancer Institute-Baylor College of Medicine-Boston Children's Hospital-Cancer Treatment Centers of America-Carilion Clinic-Case Western Reserve University-Center for Vaccine Development and Global Health, University of Maryland-Children's National Health System-Childrens Hospital Los Angeles-Cognitive Clinical Trials-Dartmouth-Hitchcock Health-Duke University/Duke Health Systems-Foundation for Sickle Cell Disease Research-HealthPartners-Henry Ford Health System-Holy Name Medical Center-Hospital of The King's Daughters Health System-Indiana University-Infirmary Health-Inova Health System-Iowa Oncology Research Association-John Hopkins University-Lifespan Health System-Medical University of South Carolina-Nephrology Associates of Northern Illinois and Indiana-New South Wales-Novant Health-Roswell Park Comprehensive Cancer Center-Rutgers Biomedical and Health Sciences-Saint Louis University-Sanford Health Clinical Research-Seattle Children's Hospital-Sound Center for Research Excellence, Inc.-Southern California Research Center-Southern Illinois University-St. Luke's Health System – Missouri-Stanford University-The Lung Research Center-The Ohio State University-The Ohio State University-Thompson Cancer Survival Center-University of Arizona-University of California Davis-University of Colorado Denver-University of Iowa-University of Maryland Greenebaum Cancer Center-University of Massachusetts Worcester-University of Michigan-University of Nebraska Medical Center-University of Oklahoma Stephenson Cancer Center-University of Pittsburgh Medical Center - Hillman Cancer Center-University of Rochester Medical Center-University of Texas MD Anderson Cancer Center-University of Texas Medical Branch-University of Utah Health Sciences-Velocity-Wayne State University-West Virginia University-Yale University

OUR TEAM

We are the Office of Regulatory Affairs, which is part of the Human Subjects Protection Program

CHLA ADVARRA EREG TEAM

Lead Administrator-Nancy Flores

eReg Administrator-Emily Benstead

Supported by our Regulatory Affairs Team

Cora Cruz, Connie Secules, Joanna Balducci & our manager, Candice Mulder

OUR TEAM

How can you contact us?

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nflores@chla.usc.edu


THANK YOU!
Any Questions?