



Clinical Research Coordinator Handbook

Welcome to your role as a Clinical Research Coordinator (CRC) in the Department of Anesthesia and Perioperative Care. The CRC role is integral to research operations at the University, and CRCs handle a wide range of tasks to support clinical research, ranging from observational to interventional studies. In the Department of Anesthesia, we support training and the continued education of CRCs. Please use this Welcome Packet as a guide to your general trainings

Week 1

CITI program:

<https://about.citiprogram.org/en/homepage/>

- Register using your UCSF email
- Complete **Good Clinical Practice** and **Human Subject Protection** Trainings
- Upload a copy of each certificate on the appropriate Teams channel for the study you are assigned to

UC learning center (via MyAccess) <https://training.ucsf.edu>

- HIPAA 101- <https://training.ucsf.edu>
- APeX training for CRCs:
https://ucsf.co1.qualtrics.com/jfe/form/SV_1zEfDDgjZ4zP7Ce
Advanced Patient-Centered Excellence (APeX) is UCSF's electronic health record, which is a version of Epic.
- HIPAA and data security for researchers- <https://irb.ucsf.edu/hipaa>
- Campus Injury and Illness Prevention Program (IIPP)
- Clinical Research Coordinator (CRC) Online Training
- Link Encounter to Research Study Document
- Safe Shipping of Biohazards/Dry Ice
- Bloodborne Pathogens Training



- Biosafety Training
- Laboratory Safety for Researchers
- UC Cyber Security Awareness Fundamentals
- UC Preventing Harassment & Discrimination Prevention: Non-Supervisors
- UCSF Foundations of Diversity, Equity, and Inclusion
- General Compliance Briefing: University of California Ethical Values and Conduct
- Working Healthy
- OnCore Introduction
 - OnCore Subject Enrollment Training-
<https://trialactivation.ucsf.edu/oncore-account-creation-training>. After you complete training, go to this website to request an account <https://hub.ucsf.edu/oncore>. Contact oncore@ucsf.edu for questions and assistance.

You do not need to file certificates of these trainings to the ISF binders. Copies of certificates are kept in learning center system.

Week 2

iRIS Training:

iRIS is the online application system you will use to submit your new study and all subsequent IRB submissions. The Human Gamete, Embryo, and Stem Cell Research Committee (GESCR) also utilizes iRIS.

There are several interactive tutorials for CRCs working in iRIS, the UCSF IRB System. To locate them, go to the UCSF IRB website's Educational Opportunities here: <https://irb.ucsf.edu/education-opportunities> and scroll down to iRIS Interactive Tutorials. You will be redirected to the iRIS Help website and must log in through MyAccess.



Trainings include:

- Introduction to the IRB Process
- iRIS 101: Homepage Orientation & Finding your IRB Forms & Documents
- Submitting a New Study
- Making Changes to Approved IRB Studies
- Responding to Linked Stipulations from the IRB

REDCap Access:

Research Electronic Data Capture (REDCap) is a secure and HIPAA-compliant web-based system for building and managing web-based research projects, such as surveys and databases. To request an account, click on the following link: <https://it.ucsf.edu/service/redcap>

Clinical Trials Operations Foundational Courses for CRCs:

The Clinical and Translational Science Institute (CTSI) supports a program of training for CRCs. It is recommended that all new CRCs start off with the Foundations Training which includes:

- CTO 100: Orientation
- CTO 101: Informed Consent
- CTO 102: IRB and Safety Training.
- CTO 103: Study Start-up and Billing
- There are several other courses offered for CRCs on a monthly basis.

To find information on the CRC Training Program go here:

<https://ctsi.ucsf.edu/programs/clinical-trials-operations/training>

You will need to verify that you have completed all the training but please note some of the training may not be applicable to you. Work with your Supervisor within the first week of hire to identify which training to complete.

UCSF My Access Platform:

MyAccess is a campus wide service providing central authentication (login) and authorization (access to UCSF systems). It allows campus units to securely identify their online customers and to properly control who has access to applications and resources. Web-based applications integrated with MyAccess will be accessible via a single login and menu page. You can favorite/bookmark specific programs by clicking “manage favorite” from the logged in homepage.



Popular applications within My Access include:

BearBuy: UCSF purchasing system

DocuSign: DocuSign is an electronic signature application that also manages routing of the document. If you are working on FDA regulated studies, ensure with IT (415 514-4100) that you are using the Part 11 Compliant DocuSign version

HBS Timekeeping System: Online timekeeping

IRB – iRIS: Institutional Review Board (IRB) submission and review

MyExpense: Employee expense reimbursement system

Qualtrics: Qualtrics allows faculty, researchers, staff and trainees to build, distribute, analyze and collaborate on complex surveys.

SmartSheet: Cloud-based project and task management system, similar to Excel sheets

UC Path: Payroll, benefits and human resources system

UCSF Box: Secure, enterprise, cloud-based storage solution.

Zoom: UCSF Zoom is a simple, all-in-one solution that lets you meet across desktops, mobile devices, and conference rooms.

Use your **UCSF username and password** to login to **MyAccess** at myaccess.ucsf.edu.

Important UCSF Websites:

We highly recommend bookmarking these websites and having them handy.

[My Access](#)

[IT Support](#)

[UC Learning Center](#)

[Clinical Research Resource HUB](#)

[UCSF IRB](#)

[Anesthesia](#)

Useful links to information & FAQs about remote access from UCSF IT

https://it.ucsf.edu/how_do/remote-work-resources

<https://it.ucsf.edu/services/vpn>

https://it.ucsf.edu/how_do/ucsf-it-security-suite



IT Support

For urgent IT support, call the UCSF IT Service Desk: (415) 514-4100.

You can submit support tickets and track existing tickets in ServiceNow: <https://help.ucsf.edu>

You can email AnesIT@ucsf.edu to reach all of Anesthesia IT. *This is appropriate for Anesthesia-specific applications or services.*

For any general IT questions, consultations, Clarity reporting requests, please contact Adam Jacobson, tel: (415) 476-6098, text: (415) 794-3334, email: Adam.Jacobson@ucsf.edu.

APeX Media Manager

To upload documents, such as Informed Consent Forms, to APeX through Media Manager, access to the P Drive is necessary. To receive access to P Drive, the Account Request Form will need to be completed by your supervisor. Please contact UCSF IT (415) 514-4100 to confirm access and troubleshooting concerns.

Care Everywhere

Care Everywhere is a Health Information Exchange that allows institutions to share electronic PHI for treatment purposes. The patient information displayed in APeX Care Everywhere belongs to the outside organization that provides it. You will be given access to Care Everywhere once your Apex account is setup

<https://irb.ucsf.edu/care-everywhere>



Voalte and Voalte Me Access

Voalte is the UCSF platform utilized for clinical care communication throughout the UCSF/ZSGF campuses. This platform is HIPAA protected. PHI for trial participants should be discussed with healthcare professionals on this platform

To gain access to VOALTE, notify your PI and Grace Wagner for set up.

Voalte Access: ARF form [UCSF ARF - Account Request Form](#)

Voalte Sign In: [VOALTE](#)

VoalteMe Access: [Voalte Me Request Form](#)

Download Voalte Me and enter Site Code: csfsfo

Voalte for EastBay Providers:

Use this link: <https://tiny.ucsf.edu/bchovoalterequest>

MD Link for Monitoring/ Audit Visit/Third Party Review

MDlink is a UCSF platform that allows non-UCSF employees to review electronic medical records. This platform is often utilized by Industry Sponsored Monitoring visits and Audit support.

Before requesting access to MDLink, review the training outline in the following link:

[MD Link and Remote Monitoring Visits: CRC and Monitor Workflow](#)



Cisco Jabber Account: Clinical Trial Telephone Use

Per department policy, CRCs will need to set up a Cisco Jabber Account with their established phone line. Personal phones utilized to contact patients is prohibited.

Contact Carlos Carrillos and Lauren Dickey for Cisco Jabber account.

Caseview:

Grants access to CRCs to view surgery schedules. Your supervisor can grant you access

Login into Caseview: <https://caseview.ucsfmedicalcenter.org/CaseView.aspx>

Weeks 2-4

Review the following documents:

[Role of CRC](#)

[Orientation Office of Clinical Research](#)

[Informed Consent Information](#)

[Research Integrity Training](#)

[Post-approval Reporting Summary](#)

[Introduction to The Regulatory Binder](#)

[Study startup resources](#)

[ALCOA+.pdf](#)



Weeks 5-6

Review the following documents:

[Research Tools and Enrollment Logs](#)

[Budgets and Coverage Analysis](#)

[Amendments and Version Control](#)

Weeks 7-8:

Review the following documents:

[Subject injury program](#)

[Research Participant payments](#)

[Recruitment methods](#)

[Investigational Drug Pharmacy Information](#)

[Clinical Trial Protocol Development](#)

[Clinical Research Services and Budgets](#)

Ongoing:

Supervisor Meetings:

If applicable, you will have a standing one-on-one meeting with your supervisor weekly or bi-weekly. During this meeting you will discuss your tasks and goals for the upcoming week and loop your supervisor in on anything you may need support with.



Team/PI Meetings:

It's strongly recommended that you meet with your PI on a weekly basis to discuss trial matters such as, subject enrollment, adverse events, protocol violations, IRB status, and queries. It is important that the PI is kept informed of all trial matters

The CRC Listserv:

Joining the **CRC Listserv**, is a great first step for CRCs. Contact CLINRESCOORD@LISTSRV.UCSF.EDU and follow the steps below to join. This listserv will regularly send out information on operational changes affecting CRCs, resources and more.

- Send a one-line email with **no subject** to listserv@listsrv.ucsf.edu the one line of the message is: **subscribe CLINRESCOORD firstnamelastname** (firstname lastname are your first and last names.) Delete all other content from the body of the message.
- The listserv server will pull your email address from the FROM field of your email. You then should receive a confirmation request email to confirm your intention to subscribe to the listserv.
- Upon confirming your subscription, you will receive a welcome/acceptance message stating that your subscription request has been accepted.

The CRC Council:

The **CRC Council** is a networking and resource sharing group for CRCs at UCSF, with broad representation across several Departments. If you are interested in being a part of the CRC Council, go here for more information: <https://irb.ucsf.edu/clinical-research-coordinators-council>



Escalation Process:

Examples of issues that should be escalated and to whom:

Example Issue:

Escalate to:

Any patient complaints	Principal Investigator and Institutional Review Board
Patient adverse events	Principal Investigator
Patient harassment	Principal Investigator and supervisor
Being asked to work more than 8 hours	Supervisor and HR
If assistant CRC, being asked to provide informed consent without PI supervision	Supervisor
Being asked to enroll ineligible patients	Supervisor
Uncooperative collaborators/stakeholders	Supervisor/ PI
Protocol violations	Principal Investigator and Institutional Review Board
Breaches of patient privacy	Principal Investigator and Institutional Review Board