UCSF
University of California
San Francisco

Suggested Training for Clinical Researchers at UCSF

#	completed	Topic	Resource	Notes	Behavioral	Observational	Interventional	Certificate/Documentation Provided	Approx. length of time to complete (min)
		New Hire and Onboarding Resources (Recommended Week 1-2)							
1		**HIPAA 101**	https://learningcenter.ucsfmedicalcenter.org/	SFMHRD2E_NEO101W_v051616	R	R	R	Yes	30
2		**HIPAA and Data Security for Researchers (IRB)**	https://hrpp.ucsf.edu/hipaa	https://hrpp.ucsf.edu/electronic-data-security	R	R	R		30
3		**CITI Human Subjects Training**	http://irb.ucsf.edu/citi-human-subjects-training	Required training for all human research studies	R	R	R	Yes	240
4		**CITI GCP**	https://www.citiprogram.org/	Good Clinical Practice training is usually optional but highly recommended	R	R	R	Yes	360
5		**Add CRC to study in systems**	Add to IRB applications via modification form in IRIS, OnCore and APEX study builds via IT ticket	PI or supervisor should assist with adding you to existing studies in IRIS, OnCore and APEX	R	R	R		45
6		**Add CRC to study documents**	Add to delegation log in regulatory binder and document training	Be sure all studies track staff duties in a delegation log	R	R	R		30
7		**Add to CRC ListServ**	http://irb.ucsf.edu/clinical-research-coordinators-council#listserv	Also contact department/division admin for other distribution lists	R	R	R		10
8		**Occupational Health Screening**	http://www.occupationalhealthprogram.ucsf.edu/ohpClin.asp	You or your supervisor must make an appointment to have health screening clearance prior to exposure to patients	R	R	R	Yes	10
9		**Review IRB Website**	http://irb.ucsf.edu/	Institutional Review Board (IRB); previously known as 'CHR'; selected links below	R	R	R		30
10		**Review The HUB Website and Training List**	http://hub.ucsf.edu/	Clinical Research Resource HUB (lots of info for CRCsR); selected links below	R	R	R		10
11		**APEX CRC Knowledge Bank and Training**	http://myapex.ucsf.edu/researchcrc	Go to UC Learning Ctr to find CRC APEX training list	a	a	R		120
12		**IRIS Intro (IRB)**	http://irb.ucsf.edu/education-opportunities	IRB training for online application system (IRIS)	C	C	C		60
		Core Training (Recommended Weeks 2-6)							
13		**Role of the CRC (IRB)**	http://irb.ucsf.edu/responsibilities-pis-and-crcs	Summary of the responsibilities of the PI and CRC	R	R	R		10
14		**Informed Consent (IRB)**	http://irb.ucsf.edu/informed-consent-discussion-and-documentation	IRB guidance on the informed consent process	R	R	R		30
15		**Informed Consent Training (HUB)**	http://hub.ucsf.edu/sites/hub.ucsf.edu/files/4a.CRCRole_Consent-part%201.pdf	http://hub.ucsf.edu/sites/hub.ucsf.edu/files/4b.Consent-part%202.pdf	C	C	C		60
16		**Research Integrity Training**	http://ori.hhs.gov/TheResearchClinic	Entertaining interactive video for training research staff	C	C	C		60
17		**Introduction to The Regulatory Binder (HUB)**	http://hub.ucsf.edu/regulatory-binder-requirements	Guidance on creation and maintaining essential documents	a	C	R		30
18		**Research Tools and Enrollment Logs (IRB)**	http://irb.ucsf.edu/research-tools-and-checklists	Templates for study logs and other study tools	R	R	R		30
19		**Data Collection and Source Documentation (HUB)**	http://hub.ucsf.edu/sites/hub.ucsf.edu/files/5.CRCRole_Documentation.pdf	Data management best practices and source documentation	R	R	R		30
20		**Study Start-up (HUB)**	http://hub.ucsf.edu/sites/hub.ucsf.edu/files/2.CRCRole_Study%20Start%20up.pdf	Describes basic steps and requirements prior to study initiation	C	C	C		30
21		**Study Start-up Checklist (HUB)**	http://hub.ucsf.edu/sites/hub.ucsf.edu/files/Study%20Start-up%20Checklist%2005oct15%5B1%5D.pdf	Steps to begin new clinical from receipt of protcol to enrollment of 1st subject	C	C	C		30
22		**Good Clinical Practice for CRCs (HUB)**	http://hub.ucsf.edu/sites/hub.ucsf.edu/files/1.CRCRole_GCP%20and%20Ethical%20Principles.pdf	Overview of GCP and ethical principals for CRCs	C	C	C		60
23		**AE Definitions and Safety Reporting (HUB)**	http://hub.ucsf.edu/sites/hub.ucsf.edu/files/6.%20Adverse%20Eventsd%20Definitions.pdf	http://hub.ucsf.edu/sites/hub.ucsf.edu/files/7.%20Reporting%20Adverse%20Events.pdf	C	R	R		60
24		**Budgets and Coverage Analysis (HUB)**	http://hub.ucsf.edu/ca-budget-billing	Describes the importance of compliant clinical research billing practices	C	C	R		30
25		**Post-approval Reporting (IRB)**	http://irb.ucsf.edu/sites/hrpp.ucsf.edu/files/post-approval-reporting-summary-sheet.pdf	A summary sheet of all AE/SAE, safety reporting, new IB, DSMB, protocol incident and violation reporting deadlines	R	R	R		30
		Supplemental and Advanced Training Resources for CRCs							
26		**IRB Audit Preparation (IRB)**	http://hrpp.ucsf.edu/sites/hrpp.ucsf.edu/files/QIU_RSV_training.pdf	http://irb.ucsf.edu/routine-site-visits-and-directed-investigations	C	C	C		30
27		**Amendments and Version Control (IRB)**	http://irb.ucsf.edu/modification	Guidance regarding protocol amendments and modification applications	C	C	C		10
28		**Participant incentive policies (IRB)**	http://irb.ucsf.edu/research-subject-payments	Guidance regarding subject payments	a	a	a		10
29		**Recruitment (IRB and HUB)**	http://irb.ucsf.edu/recruitment	http://hub.ucsf.edu/sites/hub.ucsf.edu/files/3.CRCRole_Recruitment.pdf	C	C	C		30
30		**IND Sponsor Responsibilities (HUB)**	http://hub.ucsf.edu/sites/hub.ucsf.edu/files/8.CRCRole_21CFR%20312.pdf	Drug study regulations and FDA guidance	C	a	C		10
31		**Protocol Development (HUB)**	https://hub.ucsf.edu/protocol-development	Basic information about protocol organization and development	a	a	a		10
32		**CRS Procedures and Budget Estimate**	https://accelerate.ucsf.edu/research/crs	For studies that use CRS, PCRC or other CTSI services (look up by location)	a	a	a		10
33		**Infection Control Training (UCLearning)**	https://learningcenter.ucsfmedicalcenter.org/	SFMREG4E_IC100v2012v3	R	R	R	Yes	60
34		**Bloodborne Pathogen Training (UCLearning)**	https://learningcenter.ucsfmedicalcenter.org/	SFCEHS0009C	a	a	C	Yes	60
35		**Safe Shipping (UCLearning)**	https://learningcenter.ucsfmedicalcenter.org/	SFCEHS0034C	a	a	C	Yes	30
36		**Policies for Petty Cash Handlers (UCLearning)**	https://learningcenter.ucsfmedicalcenter.org/	SFCCOD02E2013_02_25	a	a	a	Yes	60

KEY:
R = required;
C = recommended;
a= as needed, or if applicable

For any questions about this list, please email: *Liz.Garnett@ucsf.edu* *CRC Training and Resource Advisor, Office of Clinical Research*