University of California, San Francisco
Helen Diller Family Comprehensive Cancer Center

Policy for HDFCCC Investigator Training

Policy on the required clinical research training for UCSF and UCSF HDFCCC CRNO regional partner site Investigators conducting cancer related studies

Table of Contents

Purpose……..….2

Scope…….....2

Definitions…….2

Background……..2

Procedures……...3

1.0 Training Assignment……..…….3

2.0 Three Year (3-Year) Training Assignment……...3

3.0 Monitoring Compliance……..3

4.0 Training Feedback……..4

References……..…....4

Appendices……..4

University of California, San Francisco
Helen Diller Family Comprehensive Cancer Center

Purpose

This policy defines the process by which UCSF and UCSF Clinical Research Network Office (CRNO) regional partner site Investigators, conducting cancer related clinical research, receive required HDFCCC clinical research training and refresher training via the HDFCCC Data and Safety Monitoring Committee (DSMC) Education and Training Office (ETO).

Scope

This policy applies to all UCSF and UCSF CRNO regional partner site Investigators conducting cancer related trials.

Definitions

CRNO Regional Partner Site Investigators: All Investigators at the HDFCCC CRNO regional partner sites listed as "HDFCCC "Family" sites as noted on the HDFCCC Institutional Family and Outside Affiliate Institution Data Management for NCI Accrual Reporting.

Investigators Requiring Training: All Investigators conducting cancer related trials at UCSF are required to complete both the initial training and refresher trainings as long as they are an Investigator at UCSF.

Background

UCSF HDFCCC specific Investigator training was developed in 2016 to ensure that all UCSF Investigators who are conducting cancer related clinical trials receive clinical research training prior to conducting the trials in which they will be listed as an Investigator. The HDFCCC investigator training is designed to provide information on HDFCCC specific policies, workflows and infrastructure, and is intended to compliment UCSF or protocol required investigator trainings. The initial and refresher training focuses on the review of the following topics:

1. HDFCCC infrastructure (including key contacts for trial activation),
2. HDFCCC specific workflows and requirements for clinical trials,
3. Investigator responsibilities for conducting trials, and
4. HDFCCC workflows for FDA and other regulatory audits and inspections.

The Investigator training is available through University of California (UC) Learning portal, with documentation of this training provided via completion of this course.

The HDFCCC DSMC ETO website on the UCSF Wiki has information regarding required UCSF Investigator-related training, including Collaborative Institutional Training Initiative (CITI) training information required by the UCSF IRB. Investigators should review UCSF training requirements prior to participation in clinical research at UCSF.

Procedures

1.0 Training Assignment

All UCSF and UCSF HDFCCC regional partner site Investigators who are conducting cancer related studies are required, as per the HDFCCC Data and Safety Monitoring Plan (DSMP), to complete the formal HDFCCC investigator training prior to conducting any study-specific procedures for trials in which they are listed as an Investigator. This includes all Advanced Practice Providers, including Nurse Practitioners (NP) and Physician Assistants (PA).

The Site Committee is responsible for ensuring the PI has completed the required training during the initial study review, and notifying the HDFCCC DSMC ETO if the training has not been completed. The HDFCCC DSMC will assign the HDFCCC Investigator training module to the Investigator through the UC Learning portal. The Investigator will receive weekly reminder notifications via e-mail until the training has been completed. The Investigator must complete the initial training prior to conducting trials on which they are listed as an Investigator. If the Investigator does not complete the initial required training (and required refresher training), then the DSMC will review and determine remediation steps necessary to ensure completion of this required training. This may include mandating a hold on accrual for all studies being conducted by the PI. Investigators who are listed as Sub-Is and have not yet completed the initial or refresher training will not be able to initiate or continue work on the trial(s) until this training has been completed.

2.0 Three-Year (3 year) Training Updates

Investigators are required to complete the refresher every 3 years. Investigators will receive an automated notification of the requirement to complete this retraining within 60 calendar days of the expiry of their training period. Investigators will continue to receive this automated e-mail notification on a weekly basis until the training has been completed. The DSMC ETO will also receive these notifications and will follow-up with the Investigators if the 3 year training certification timeline has expired to ensure that this training is completed. If the investigator refresher training has not been completed after a month of the expiration of their initial or refresher training, then the DSMC will review and determine necessary remediation steps necessary to ensure completion of this required training. This remediation may include mandating a hold on accrual for all studies being conducted by the PI. Investigators who are listed as Sub-Is and have not yet completed the refresher training will not be able to initiate or continue work on the trial(s) until this training has been completed.

3.0 Monitoring Compliance

The DSMC ETO will track initial and refresher training for all Investigators conducting cancer related clinical research.

The DSMC ETO will follow-up with the Investigators who are delinquent in this training to remind them of potential remediation steps necessary to ensure completion of this required training. The DSMC ETO will provide a listing from UC Learning of the Investigator Training status on a weekly basis, which will highlight which Investigators have lapsed training. All Pis and Sub-Investigators cannot open a new trial or continue to work on the trial until the initial and/or refresher training has been completed.

4.0 Training Feedback

After completion of the training, Investigators will receive a link to a Qualtrics Survey to provide their feedback on the training, noting recommendations for future topics of training, effectiveness of current training, and follow-up questions from the training. The DSMC ETO will follow-up with any Investigator who has additional questions after the training. The other results from the survey will be utilized for modifications and additions to the current training.

Policy Exemptions
The initial investigator training was rolled out in 2016, but the investigator refresher training was not available until June 2023, so the greater than 3-year delay in the refresher training for all applicable Investigators was due to the delay in the development and approval of this refresher training.

References

- CITI Training
- HHS Regulations for the Protection of Human Subjects in Research (45CFR46)
- Helen Diller Family Comprehensive Cancer Center Data and Safety Monitoring Plan (DSMP).
- https://wiki.library.ucsf.edu/display/HCR/DSMC+Education+and+Training+Office
- 21 CRF 312.53.

Appendices

None

Policy Approval

This policy document was approved by the following personnel on the following dates:

DocuSigned by:
Eric Small
7FCB32D327E3438...

9/2/2023

Eric Small, MD
Deputy Director
Helen Diller Family Comprehensive Cancer Center

Date

DocuSigned by:
Kate Shumate
80D38159E89D41B...

9/4/2023

Kate Shumate, MPA, CCRP
Director, Administration and Planning
Helen Diller Family Comprehensive Cancer Center

Date

DocuSigned by:
Katie Kelley
7F538467F93949B...

9/1/2023

Katie Kelley, MD
Chair, Data and Safety Monitoring Committee
Helen Diller Family Comprehensive Cancer Center

Date

Policy Contact:

John McAdams
DSMC Director
John.McAdams@ucsf.edu

DocuSign

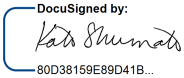
Certificate Of Completion

Envelope Id: 2D39C22C2370405EBD953E1BA9EBBA3F
Status: Completed
Subject: Complete with DocuSign: HDFCCC Policy for Investigator Training (version 01Sep2023).doc
Source Envelope:
Document Pages: 5
Signatures: 3
Certificate Pages: 2
Initials: 0
AutoNav: Enabled
EnvelopeId Stamping: Disabled
Time Zone: (UTC-08:00) Pacific Time (US & Canada)

Envelope Originator:
John Mcadams
1855 Folsom St
Suite 601
San Francisco, CA 94103
John.McAdams@ucsf.edu
IP Address: 128.218.42.204

Record Tracking

Status: Original
9/1/2023 6:56:14 PM
Holder: John Mcadams
John.McAdams@ucsf.edu
Location: DocuSign

Signer Events	Signature	Timestamp
Eric Small Eric.Small@ucsf.edu Professor University of California, San Francisco Security Level: Email, Account Authentication (Optional) **Electronic Record and Signature Disclosure:** Not Offered via DocuSign	DocuSigned by:  7FCB32D327E3438... Signature Adoption: Pre-selected Style Using IP Address: 76.126.140.231	Sent: 9/1/2023 6:59:23 PM Viewed: 9/2/2023 9:07:06 AM Signed: 9/2/2023 9:07:23 AM
Katherine Shumate kate.shumate@ucsf.edu Chief of Staff, Director of Administration University of California, San Francisco Security Level: Email, Account Authentication (Optional) **Electronic Record and Signature Disclosure:** Not Offered via DocuSign	DocuSigned by:  80D38159E89D41B... Signature Adoption: Uploaded Signature Image Using IP Address: 128.218.42.106	Sent: 9/1/2023 6:59:24 PM Viewed: 9/4/2023 3:16:25 PM Signed: 9/4/2023 3:16:39 PM
Katie Kelley katie.kelley@ucsf.edu MD University of California, San Francisco Security Level: Email, Account Authentication (Optional) **Electronic Record and Signature Disclosure:** Not Offered via DocuSign	DocuSigned by:  7F538467F93949B... Signature Adoption: Pre-selected Style Using IP Address: 73.202.35.124 Signed using mobile	Sent: 9/1/2023 6:59:24 PM Viewed: 9/1/2023 8:39:57 PM Signed: 9/1/2023 8:40:04 PM

In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	9/1/2023 6:59:24 PM
Certified Delivered	Security Checked	9/1/2023 8:39:57 PM
Signing Complete	Security Checked	9/1/2023 8:40:04 PM
Completed	Security Checked	9/4/2023 3:16:39 PM

Payment Events	Status	Timestamps