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

Delegation of Authority (DOA) Log Completion Policy

Study Personnel Master Signature Page and Study-Specific Delegation of Authority Log completion instructions

Purpose

The purpose of this policy is to outline which study staff are required to have a Study Personnel Master Signature Page and be listed on the Study-Specific Delegation of Authority (DOA) Log for all therapeutic and non-therapeutic studies conducted at the UCSF Helen Diller Family Comprehensive Cancer Center (HDFCCC), including observational, ancillary, and correlative trials. Faculty and staff who participate in clinical trials conducted by the HDFCCC, and are qualified to perform duties, will be delegated specific duties by the Principal Investigator (PI) on the Study-Specific DOA log, and will record their signature and initials on the Study Personnel Master Signature Page.

Scope

As per the following FDA guidance document: *Guidance for Industry: Investigator Responsibilities –Protecting the Rights, Safety, and Welfare of Study Subjects (https://www.fda.gov/downloads/Drugs/.../Guidances/UCM187772.pdf*), the PI is ultimately accountable for the performance and supervision of a clinical investigation. While the PI may delegate some required tasks to sub-investigators and other research staff (e.g., Clinical Research Coordinators, Pharmacists, etc.), the PI remains accountable for their conduct (as per Title 21 of the Code of Federal Regulations Subpart D 312.53) and is responsible for regulatory violations resulting from failure to adequately supervise the conduct of the clinical trial.

The Study-Specific DOA Log lists all of the study staff, including the Investigators and Clinical Research Coordinators (CRCs), and other designated site personnel who are delegated significant trial-related duties from the PI. The Study-Specific DOA Log must be completed for all therapeutic and non-therapeutic trials conducted in the HDFCCC. The Study Personnel Master Signature Page contains the name, signature and initials for all staff listed on the Study-Specific DOA log.

Background

The PI is responsible for the overall conduct of the clinical trial, but may delegate specific tasks to qualified and trained study staff. Only appropriately qualified individuals to whom the Investigator has delegated significant trial-related tasks will be entered on the Study-Specific DOA Log.

References

Title 21 CFR 312.53 – Selecting Investigators and Monitors
Title 21 CFR 312.60 – General Responsibilities of Investigators
Title 21 CFR 812(e) – Responsibilities of Investigators
ICH GCP E6 Guidelines
Guidance for Industry: Investigator Responsibilities –Protecting the Rights, Safety, and Welfare of Study Subjects

Appendices

Appendix 1: Study Personnel Master Signature Page
Appendix 2: Study-Specific Delegation of Authority Log
Appendix 3: Delegation of Authority Log Duty Assignment Guideline
Appendix 4: Note to File

Procedures

1.0 Study Personnel Master Signature Page

Individuals who are delegated significant research related tasks on any clinical trial conducted at the HDFCCC will complete a Study Personnel Master Signature Page (Appendix 1). Only one page needs to be completed for each staff, regardless of the number of trials to which he/she is assigned.

The start date on the Study Personnel Master Signature Page for all individuals whose employment date precedes the implementation of the Study Personnel Master Signature Page will be December 01, 2018. Following the effective date of this policy, the start date on the Study Personnel Master Signature Page will be an individual's first day of employment in a role that requires the individual to perform significant research related tasks. In the event that an employee's name changes, the original Master Signature Page will be archived for the initial name and a new Study Personnel Master Signature Page with the individual's new name and start date will be completed.

2.0 Study-Specific Delegation of Authority (DOA) Log

Each clinical trial must have its own Study-Specific DOA log (Appendix 2). Study-Specific DOA logs must be completed for all therapeutic and non-therapeutic industry, cooperative group (i.e., NCI) and investigator- initiated clinical trials conducted in the HDFCCC. The PI is responsible for selecting appropriately qualified study staff. The selection of appropriately qualified study staff for significant trial related duties is as per *ICH GCP 4.1.5*. Certain duties may only be performed by qualified individuals as permitted by local law, medical or standard of care practices, or applicable required training as per job descriptions or designations. Suggested guidelines for task assignments can be found in Appendix 3. The PI may specify "other" responsibilities if required by the protocol or study sponsor. The primary Clinical Research Coordinator assigned to the trial is responsible for ensuring that the Study-Specific DOA log is completed and updated at all times.

The Study-Specific DOA log will be implemented for all new studies open to accrual as of December 01, 2018. Prior to this policy revision, studies used sponsor provided DOA logs or a HDFCCC template. For all trials opened to accrual before December 01, 2018, the Study-

Specific DOA log will be created and previous DOA logs will be decommissioned as per the Note-to-file in Appendix 4. Appendix 4 will be filed in all study-specific regulatory binders along with the decommissioned DOA.

The Study-Specific DOA log will list all the assigned study staff members, along with each of their delegated tasks, start date and end date on the study. The start date must precede the performance of any study specific tasks. The stop date on the Study-Specific DOA log for all individuals assigned to the clinical trial will be the date they are no longer assigned to work on the clinical trial in the assigned role, including termination of employment. In the event that the individual's role changes, a stop date will be entered for the initial role and a new entry will be made on the Study-Specific DOA log with the individual's new role and start date.

The Principal Investigator must initial the start and stop dates of all staff confirming delegated tasks and dates of participation in the clinical trial on the Study-Specific DOA log. The Principal Investigator will sign the attestation at the bottom of the Study-Specific DOA log prior to consenting the first patient in order to confirm that the tasks have been appropriately delegated. Any staff added to the Study-Specific DOA log after this date will be covered under this signature as long as the PI's initials are beside the start date. The PI will sign the Study-Specific DOA log at the end of the clinical trial (prior to terminating the study with the IRB of record), confirming his/her oversight over the duration of the trial.

In the event of a change in PI during the trial, a stop date will be added for all staff listed on the Study-Specific DOA log and a new Study-Specific DOA log will be created with the new PI delegating responsibility to staff. The end date on the previous Study-Specific DOA log and the start date on the new Study-Specific DOA log will be the date the IRB confirmed the change in PI.

2.1 UCSF IRB of Record

Only study staff listed on the UCSF IRB application in sections 3.2A as Key Study Personnel (KSP)/Additional Investigators (i.e., Sub-Investigators and Nurse Practitioners) and section(s) 3.2B as Research Support Staff (i.e., Clinical Research Coordinators (CRCs), Protocol Project Managers (PPMs), Pharmacists, etc.) will be listed on the Study-Specific DOA Log for all trials conducted in the HDFCCC. Non-research staff who perform only research specific procedures in connection with the protocol and which follow the scope of practice assigned to the specific role (e.g., Phlebotomists, EKG Technicians, Lab Technicians, Interventional Radiologists, Infusion Center Nursing Staff, In-Patient nurses, Pharmacy Technicians, Medical Assistants, etc.) are not required to sign the Study Personnel Master Signature Page or the Study-Specific DOA Log as per the ICH GCP Guidelines in section 4.1.5, as these individuals are not performing significant trial-related duties and do not require study specific training to perform these procedures.

Additionally, Hospitalists, non-research Nurse Practitioners, Residents, or Fellows who only provide ancillary or intermittent care for the study patients, but do not make a direct or significant contribution to the clinical data (i.e., evaluate AEs, sign drug order forms, consent study patients, etc.) are not required to be listed on the Study-Specific DOA Form. All progress notes not signed by a study team member listed on the KSP will be reviewed and signed by an Investigator.

2.2 Central Institutional Review Board (CIRB)

All staff rostered with CIRB will be listed on the Study-Specific DOA Log for all trials conducted at the HDFCCC.

2.3 Other External IRBs (i.e. outside UCSF)

Study teams should defer to outside IRB requirements. At minimum, study investigators (Principal Investigators, Sub-Investigators and Nurse Practitioners) and research support staff (CRCs, PPMs, Pharmacists, etc.) should be included on the Study-Specific DOA log.

3.0 Storage

The Study Personnel Master Signature Page will be uploaded into the electronic regulatory platform used by the HDFCCC (Complion) in the central binder. The wet-ink document will be destroyed after it is uploaded into Complion. In the event an employee changes their last name, a new Study Personnel Master Signature Page will be uploaded into the central binder and the original form will be marked as Archived

The Study-Specific DOA log is maintained as a wet-ink original document in the study specific regulatory binder and is available to external sponsors, auditors and/or inspectors upon request; electronic copies will be provided to external sponsors, auditors and/or inspectors though the study specific binder in Complion.

Alternate Procedure

New sponsor provided DOA logs would no longer be completed as of December 01, 2018. Previous sponsor provided DOA logs will be decommissioned as per Appendix 4.

Single Patient INDs do not require a DOA log.

There are no alternate procedures to this policy document. FOR IRB POLICIES, ALWAYS CHECK THE UCSF HRPP WEBSITE FOR FORMS AND GUIDANCE.

http://irb.ucsf.edu

Policy Approval

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

DocuSigned by:
Kate Shumate
80D38159E89D41B...

11/9/2018

Kate Shumate, MBA
Chief of Staff
Director, Administration and Planning
UCSF, Helen Diller Family Comprehensive Cancer Center

Date

DocuSigned by:
Charalambos Andreadis
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11/10/2018

Charalambos Andreadis, MD
Clinical Research Support Office Medical Director
UCSF, Helen Diller Family Comprehensive Cancer Center

Date

DocuSigned by:
Eric Small
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11/10/2018

Eric Small, MD
Chief Scientific Officer
Deputy Director, HDFCCC
UCSF, Helen Diller Family Comprehensive Cancer Center

Date

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

Policy Revision Summary of Changes

Policy Title:	**Delegation of Authority (DOA) Log Completion Policy**
Version Date:	October 24, 2018
Version Number:	Revision 1

Notes: Page number corresponds to page number in updated version (Revision 3). New text in modified paragraphs is shown as ***bold italics*** and deleted text is shown as ~~strikethrough~~.

Page No.: 1-4	**Section**: All sections
Original Text	N/A
New Text	Addition of Master Signature Page throughout policy
Reason for Change	The Master Signature log will be completed one time for all HDFCCC research staff to document their start-date, signature and hand-writing sample. Other than the Principal Investigator, all other signatures have been removed from the Study-Specific Delegation of Authority log.

Page No.: 1	**Section**: Purpose
Original Text	The purpose of this policy is to outline which study staff are required to be listed on the Delegation of Authority (DOA) Log for all therapeutic and non-therapeutic clinical trials conducted at the UCSF Helen Diller Family Comprehensive Cancer Center (HDFCCC).
New Text	The purpose of this policy is to outline which study staff are required to ~~be listed on the~~ **have a Study Personnel Master Signature Page and be listed on the Study-Specific** Delegation of Authority (DOA) Log for all therapeutic and non-therapeutic ~~clinical~~ **studies** conducted at the UCSF Helen Diller Family Comprehensive Cancer Center (HDFCCC), **including observational, ancillary, and correlative trials. Faculty and staff who participate in clinical trials conducted by the HDFCCC, and are qualified to perform duties, will be delegated specific duties by the Principal Investigator (PI) on the Study-Specific DOA log, and will record their signature and initials on the Study Personnel Master Signature Page.**
Reason for Change	Further details and clarification added to describe when the Study-Specific Delegation of Authority Log needs to be completed and who should be documented on the log.

Page No.: 1-4	**Section**: All sections
Original Text	Delegation of Authority (DOA) Log
New Text	**Study-Specific** Delegation of Authority (DOA) Log
Reason for Change	Reflects the new name of the document. The revised Study-Specific DOA log can be found in Appendix 2.

Page No.: 1	**Section**: Scope
Original Text	While the PI may delegate some required tasks to sub-investigators and other research staff, the PI remains accountable for their conduct.
New Text	While the PI may delegate some required tasks to sub-investigators and other research staff **(e.g., Clinical Research Coordinators, Pharmacists, etc.)**, the PI remains accountable for their conduct **(as per Title 21 of the Code of Federal Regulations Subpart D 312.53) and is responsible for regulatory violations resulting from failure to adequately supervise the conduct of the clinical trial.**
Reason for Change	Clarification on PI oversight responsibility

Page No.: 2-3	**Section**: Procedures
Original Text	The DOA log will list all the assigned study staff members, along with each of their delegated tasks. The study staff members must initial and date the DOA log and enter their delegated tasks on this log. The PI will then sign and date the delegated study staff member's entry on the log.

New Text	**Certain duties may only be performed by qualified individuals as permitted by local law, medical or standard of care practices, or applicable required training as per job descriptions or designations. Suggested guidelines for task assignments can be found in Appendix 3. The PI may specify "other" responsibilities if required by the protocol or study sponsor. The primary Clinical Research Coordinator assigned to the trial is responsible for ensuring that the Study-Specific DOA log is completed and updated at all times.** **The Study-Specific DOA log will be implemented for all new studies open to accrual as of December 01 15, 2018. Prior to this policy revision, studies used sponsor provided DOA logs or a HDFCCC template. For all trials opened to accrual before December 01, 2018, the Study-Specific DOA log will be created and previous DOA logs will be decommissioned as per the Note-to-file in Appendix 4. Appendix 4 will be filed in all study specific regulatory binders along with the decommissioned DOA.** The **Study-Specific** DOA log will list all the assigned study staff members, along with each of their delegated tasks, **start date and end date on the study. The start date must precede the performance of any study specific tasks. The stop date on the Study-Specific DOA log for all individuals assigned to the clinical trial will be the date they are no longer assigned to work on the clinical trial in the assigned role including termination of employment. In the event that the individual's role changes, a stop date will be entered for the initial role and a new entry will be made on the Study-Specific DOA log with the individual's new role and start date.** **The Principal Investigator must initial the start and stop dates of all staff confirming delegated tasks and dates of participation in the clinical trial on the Study-Specific DOA log. The Principal Investigator will sign the attestation at the bottom of the Study-Specific DOA log prior to consenting the first patient in order to confirm that the tasks have been appropriately delegated. Any staff added to the Study-Specific DOA log after this date will be covered under this signature as long as the PI's initials are beside the start date. The PI will sign the Study-Specific DOA log at the end of the clinical trial (prior to terminating the study with the IRB of record), confirming his/her oversight over the duration of the trial.** **In the event of a change in PI during the trial, a stop date will be added for all staff listed on the Study-Specific DOA log and a new Study-Specific DOA log will be created with the new PI delegating responsibility to staff. The end date on the previous Study-Specific DOA log and the start date on the new study specific DOA log will be the date the IRB confirmed the change in PI.**

	~~The study staff members must initial and date the DOA log and enter their delegated tasks on this log. The PI will then sign and date the delegated study staff member's entry on the log.~~
Reason for Change	Additional details on how to complete the Study-Specific DOA log added. Instructions for implementing the new Study-Specific DOA log and decommissioning previous logs added.

Page No.: 3-4	**Section**:
Original Text	Non-research staff who perform only research specific procedures in connection with the protocol and which follow the scope of practice assigned to the specific role (e.g., Phlebotomists, EKG Technicians, Lab Technicians, Interventional Radiologists, Infusion Center Nursing Staff, Medical Assistants, etc.) are not required to DOA Log as per the ICH GCP Guidelines in section 4.1.5, as these individuals are not performing significant trial-related duties and do not require study specific training to perform these procedures…. Additionally, the PI is responsible for ensuring that updates to the DOA log for clinical research personnel changes are completed in a timely manner by the corresponding study staff.
New Text	Non-research staff who perform only research specific procedures in connection with the protocol and which follow the scope of practice assigned to the specific role (e.g., Phlebotomists, EKG Technicians, Lab Technicians, Interventional Radiologists, Infusion Center Nursing Staff, **In-Patient nurses, Pharmacy Technicians**, Medical Assistants, etc.) are not required to **sign the Study Personnel Master Signature Page** ~~be listed on the~~ **or the Study-Specific** DOA Log as per the ICH GCP Guidelines in section 4.1.5, as these individuals are not performing significant trial-related duties and do not require study specific training to perform these procedures… **All progress notes not signed by a study team member listed on the KSP will be reviewed and signed by an Investigator.** ~~Additionally, the PI is responsible for ensuring that updates to the DOA log for clinical research personnel changes are completed in a timely manner by the corresponding study staff.~~
Reason for Change	Add additional roles which do not need to be listed on the Study-Specific DOA log. Clarify oversight by PI when notes are written by someone not included as part of the study team. Process for updating the log moved to an earlier section and removed from the current section.

Page No.: 4	**Section**: Procedures
Original Text	N/A

New Text	**2.2 Central Institutional Review Board (CIRB)** **All staff rostered with CIRB will be listed on the Study-Specific DOA Log for all trials conducted at the HDFCCC.** **2.3 Other External IRBs (i.e. outside UCSF)** **Study teams should defer to outside IRB requirements. At minimum, study investigators (Principal Investigators, Sub-Investigators and Nurse Practitioners) and research support staff (CRCs, PPMs, Pharmacists, etc.) should be included on the Study-Specific DOA log.**
Reason for Change	Specific instructions for who to include on the Study-Specific DOA log when an outside IRB (non-UCSF) is used as the IRB of record.

Page No.: 4	**Section**: Procedures
Original Text	N/A
New Text	**The Study Personnel Master Signature Page will be uploaded into the electronic regulatory platform used by the HDFCCC (Complion) in the central binder. The wet-ink document will be destroyed after it is uploaded into Complion. In the event an employee changes their last name, a new Study Personnel Master Signature Page will be uploaded into the central binder and the original form will be marked as Archived** **The Study-Specific DOA log is maintained as a wet-ink original document in the study specific regulatory binder and is available to external sponsors, auditors and/or inspectors upon request; electronic copies will be provided to external sponsors, auditors and/or inspectors though the study-specific binder in Complion.**
Reason for Change	New text. Details on storage of all documented added.

Page No.: 4	**Section**: Alternate Procedure
Original Text	N/A
New Text	**New sponsor provided DOA logs would no longer be completed as of December 01, 2018. Previous sponsor provided DOA logs will be decommissioned as per Appendix 4.** **Single Patient INDs do not require a DOA log.**
Reason for Change	New text. Alternate procedure added. Sponsor provided DOA logs will no longer be completed.

Page No.: 5	**Section**: Policy Approval
Original Text	Thierry Jahan, MD Chair, Data and Safety Monitoring Committee

New Text	**Charalambos Andreadis, MD** **Clinical Research Support Office Medical Director**
Reason for Change	Changed policy approver/signatory to the Clinical Research Support Office (CRSO) Director as the research personnel included on the Study-Specific DOA log are under the direction of the CRSO.

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

Delegation of Authority (DOA) Log Completion Policy

Appendix 1: Study Personnel Master Signature Page

Name:	
Signature:	Initials:
Writing Sample (0-9)	
Date of affiliation to HDFCCC (mm/dd/yyyy):	

UCSF Helen Diller Family Comprehensive Cancer Center

Delegation of Responsibility / Authority Log

CC#:	Sponsor:			PI:		
NAME (printed)	**ROLE**	**RESPONSIBILITIES (Enter all number keys* that apply)**	**START DATE**	**PI INITIALS & DATE**	**STOP DATE**	**PI INITIALS & DATE**
	Principal Investigator					
	❑Sub-Investigator ❑ Coordinator ❑Pharmacist ❑ Lab Director ❑ Research Nurse ❑ Nurse Practitioner ❑ Other (specify):					
	❑Sub-Investigator ❑ Coordinator ❑Pharmacist ❑ Lab Director ❑ Research Nurse ❑ Nurse Practitioner ❑ Other (specify):					
	❑Sub-Investigator ❑ Coordinator ❑Pharmacist ❑ Lab Director ❑ Research Nurse ❑ Nurse Practitioner ❑ Other (specify):					
	❑Sub-Investigator ❑ Coordinator ❑Pharmacist ❑ Lab Director ❑ Research Nurse ❑ Nurse Practitioner ❑ Other (specify):					
	❑Sub-Investigator ❑ Coordinator ❑Pharmacist ❑ Lab Director ❑ Research Nurse ❑ Nurse Practitioner ❑ Other (specify):					
	❑Sub-Investigator ❑ Coordinator ❑Pharmacist ❑ Lab Director ❑ Research Nurse ❑ Nurse Practitioner ❑ Other (specify):					
	❑Sub-Investigator ❑ Coordinator ❑Pharmacist ❑ Lab Director ❑ Research Nurse ❑ Nurse Practitioner ❑ Other (specify):					
	❑Sub-Investigator ❑ Coordinator ❑Pharmacist ❑ Lab Director ❑ Research Nurse ❑ Nurse Practitioner ❑ Other (specify):					

Responsibilities*

1. Consent/Assent procedures
2. Determine subject eligibility
3. Perform study assessments
4. Evaluate study assessments
5. Perform physical examinations
6. Investigational product preparation
7. Investigational product administration
8. Investigational product receipt/return/accountability
9. Collect AE/SAE data
10. Assess AE/SAE causality, attribution, severity
11. Report Serious Adverse Events (SAEs)
12. Maintenance of Investigator site file/regulatory documents
13. Communication with the IRB
14. Lab procedures and/or collection for testing
15. CRF completion/revisions
16. Data query resolution
17. IVRS/IWRS entry
18. Other (specify):
19. Other (specify):
20. Other (specifiy):
21. Other (specifiy):
22. Other (specifiy):

Prior to Study Start:

1. I have ensured that the individuals listed above are properly qualified and have received appropriate training related to their respective tasks.
2. I have delegated the indicated responsibilities to the individuals listed above and assert that these duties were performed under my direct supervision.
3. I understand that the overall responsibility for the conduct of the research remains with me.

PI's Signature Acknowledging Delegation of Authority and Study-Specific Training: ____ Date: ________________________________

(to be signed prior to first patient consent)

Study Completion:

I ______________________________(PI Name), for the protocol identified above, verify that the delegated tasks were performed under my supervision. PI Signature:____

UCSF Helen Diller Family Comprehensive Cancer Center

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

Delegation of Authority (DOA) Log Completion Policy

Appendix 3: Delegation of Authority Log Duty Assignment Guideline

Number	Duty	Standard Definition	PI	Sub-I	Pharmacist	Research Nurse	Coordinator[3]	Lab Director	Other
1	Consent/assent procedures	Review, conduct and document the informed consent process with the participant	X	X		X[1]	X[1]		
2	Determine subject eligibility	Review, verify and document that participant meet all inclusion and exclusion criteria	X	X					
3	Perform study assessments	Conduct study related assessments in accordance with protocol requirements	X	X		X	X[2]		
4	Evaluate study assessments	Review, evaluate and document study assessments in accordance with protocol requirements	X	X					
5	Perform physical examinations	Conduct physical examinations in accordance with protocol requirements	X	X					
6	Investigational product (IP) preparation	Follow protocol (or pharmacy manual) instructions for preparation of IP.	X	X	X				
7	Investigational product (IP) administration	Utilize protocol required IP assignment system (e.g. IWRS) to assign IP to participant and dispense as per study guidelines.	X	X	X				
8	Investigational product (IP)	Follow instructions for IP storage, accountability and destruction	X	X	X				

Number	Duty	Standard Definition	PI	Sub-I	Pharmacist	Research Nurse	Coordinator[3]	Lab Director	Other
	receipt/return/ accountability								
9	Collect AE/SAE data	Collect progress notes, labs, etc. to document AE/SAE	X	X		X	X		
10	Assess AE/SAE causality, attribution, severity	Determine the relationship to IP, expectedness and severity of AE/SAE	X	X					
11	Report Serious Adverse Events (SAE)	Report SAE to sponsor (data entry)	X	X		X	X		
12	Maintenance of Investigator site file/regulatory documents	Collect and maintain all regulatory files as required by the sponsor, UCSF policies, GCP and FDA regulations	X	X			X		
13	Communication with IRB	Prepare and submit documents to IRB of record (either directly or via CRSO regulatory). Respond to requests for information, revisions or general inquiries.	X	X			X		CRSO Regulatory team
14	Lab procedures and/or collection for testing	Collect and analyze lab samples as per study protocol	X	X				X	
15	CRF completion/ revisions	Enter protocol required data into CRFs/EDC.	X	X		X	X		
16	Data query resolution	Resolve all queries issued by the sponsor in the CRFs/EDC	X	X		X	X		
17	IVRS/IWRS entry	Make role-specific calls to IVRS / enter role-specific data in IWRS	X	X	X	X	X		

Number	Duty	Standard Definition	PI	Sub-I	Pharmacist	Research Nurse	Coordinator[3]	Lab Director	Other
18-22	Other	Specify tasks and assign role based on training and scope of practice							

[1]Non-therapeutic studies only with appropriate approval and training as per Informed Consent Policy.
[2]Must be within scope of practice and training e.g. administer questionnaires
[3]Includes Lead Clinical Research Coordinators (CRC), CRC and Protocol Project Managers (PPMs). Tasks may differ according to job title.

UCSF Helen Diller Family Comprehensive Cancer Center

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

Delegation of Authority (DOA) Log Completion Policy

Appendix 4: Note to File

The Study-Specific Delegation of Authority (DOA) Log, as per revised HDFCCC policy titled "Delegation of Authority (DOA) Log Completion Policy" (Revision 1 – Effective 12/01/2018) will be created as per the following processes:

1. Site Committee Administrator for each site committee will have all research staff sign the Study Personnel Master Signature Page at their Site Committee Meeting. The Site Committee Administrators will upload into Complion.
2. Trials opening to accrual on or after December 01, 2018:
    a. Study-Specific DOA log will be created by the study assigned staff and signed by the Principal Investigator before any study specific tasks are completed. Sponsor provided DOA logs will no longer be completed.
    b. Study assigned staff will ensure all staff listed on the Study-Specific DOA log have a Master Signature Page uploaded in Complion. If no Master Signature Page is available, the staff will ensure the page is signed and uploaded.
3. Trials currently open to accrual (i.e. open to accrual before December 01, 2018):
    a. Study-Specific DOA log will be created by the study assigned staff and signed by the Principal Investigator by **February 01, 2019**.
    b. Study assigned staff will ensure all staff listed on the Study-Specific DOA log have a Master Signature Page uploaded in Complion. If no Master Signature Page is available, the staff will ensure the page is signed and uploaded.
    c. The staff will decommission any previous versions of the DOA log by putting the end date for all staff as the date the new Study-Specific DOA log was signed by the PI. The staff should ensure any other relevant signatures are. The staff will file this Note to File with the decommissioned and complete the bottom section of this Note to File with the relevant details.
    d. The decommissioned DOA log, Note to file and new Study Specific DOA log will be filed in the study specific regulatory binder.
4. Trials currently open (i.e. in follow-up) but closed to accrual (i.e. closed to accrual before December 01, 2018):
    a. Study-Specific DOA log will be created by the study assigned staff and signed by the Principal Investigator by **April 01, 2019**.
    b. Study assigned staff will ensure all staff listed on the Study-Specific DOA log have a Master Signature Page uploaded in Complion. If no Master Signature Page is available, the staff will ensure the page is signed and uploaded.
    c. The staff will decommission any previous versions of the DOA log by putting the end date for all staff as the date the new Study-Specific DOA log was signed by the PI. The staff should ensure any other relevant signatures are. The staff will file this Note to File with the decommissioned and complete the bottom section of this Note to File with the relevant details.
    d. The decommissioned DOA log, Note to file and new Study Specific DOA log will be filed in the study specific regulatory binder.

CC# _____

Date new Study Specific DOA log effective (mm/dd/yyyy): _____

Date previous DOA log was decommissioned (mm/dd/yyyy): _____