UCSF Helen Diller Family Comprehensive Cancer Center

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

Policy for Verbal Notification of New High Risk Adverse Events

Table of Contents

Purpose

The purpose of this Helen Diller Family Comprehensive Cancer Center (HDFCCC) policy is to detail the verbal notification process of new high risk adverse events (AEs) prior to re-consent with an updated informed consent form.

Scope

This policy applies to all participants on interventional trials conducted in the HDFCCC (irrespective of sponsor type).

Definitions

None

Background

Throughout the course of an interventional clinical trial, new information on the risks of intervention become known to sponsors and investigators. These risks must be communicated to potentially impacted participants in a timely manner as part of the informed consent process. Ideally, these participants would receive this communication via a new consent discussion, including provision and signature of a revised consent form updated with the new risk information. However, in some instances (due to the acuity or nature of the new risk(s) identified), an investigator may deem it necessary to alert participants to new risk information more quickly than the time in which an amended consent form can be generated. In such an instance, verbal notification as described in this policy is an effective way to communicate the new risks and thereby ensure transparency with participants regarding their safety.

Procedures

1.0 Notification of New Risk AEs

It is the responsibility of the sponsor to identify all new risks and distribute it to all participating study sites and investigators. Refer to the HDFCCC External Adverse Event Report Management Policy for requirements, sponsor responsibilities, and procedures for retrieving and processing external new risk information.

2.0 Determination of New Risk AEs as High Risk

Determinations of “high risk” is made the by Principal Investigators (PI) at their discretion and best judgement. The PI may determine a new AE is “high risk” if it changes the risk/benefit ratio or are significant and immediate.

Examples of high risks requiring verbal notification may include, but are not limited to, life threatening or requiring immediate medical attention such as grade 4 neutropenia, grade 4 thrombocytopenia, liver/kidney failure and pancreatic failure.

A new risk is only considered “high risk” if the study PI makes an explicit “high risk” determination after reviewing new risk information. Sub-investigators are permitted to determine high risk in the absence of the study PI.

3.0 Verbal Notification of On-Treatment Participants

To ensure participants are provided adequate information to determine whether they want to continue participation in the study, the PI or authorized member(s) of the study team must verbally notify each participant on the study treatment impacted by that new high risk, prior to their next infusional treatment or before the next dispensation for oral treatment. Participants who have discontinued therapy within 30 days prior to the high risk notification should also be notified within a reasonable time-frame as determined by the PI.

For participants on self-administered oral agents, participants must be notified before their next dispensation after the date of determination of high risk. If the participant cannot be reached, appropriate attempts to contact must be made and documented. For non- English speaking participants, a translator is required during verbal notification of new high risk AEs.

4.0 Participant Reconsent

Once the revised ICF containing new risk is approved by the IRB of record, all participants impacted by the new risk change must be reconsented (regardless of whether verbal notification has taken place or not). Participants off treatment for more than 30 days may not require re-consent and should follow the process in the HDFCCC Policy for Obtaining Informed Consent of Potential Patients for Therapeutic and Non-Therapeutic Oncology Clinical Trials.

5.0 Participant Consent Withdrawal

If a participant is verbally notified of new high risk(s) and subsequently withdraws consent from the study prior to IRB approval of the updated ICF, the participant does not need to be reconsented. The verbal notification, as a continuation of the consent process, will satisfy the requirement to notify the participant.

6.0 Off-Treatment Participants

PIs must evaluate newly identified high risk AEs to determine whether off-treatment participants (participants who completed the treatment portion of the study, as defined in the protocol) need to be verbally notified. Participants who are off treatment must be verbally notified of the risk only when determined appropriate by the study PI. Participants who have discontinued treatment within the past 30 days are considered active on the clinical trial, and the PI should verbally notify them along with on-treatment participants as noted in section 3.0. Participants on long-term or survival follow-up are not verbally notified, unless otherwise indicated by the PI and/or the IRB.

7.0 Documentation of Verbal Notification

After each verbal notification, the PI or authorized member(s) must document the conversation in the UCSF medical record and/or research chart and indicate the participant's willingness to continue in the study.

Policy Exemptions

If there is an approved Institutional Review Board (IRB) updated informed consent form (ICF) available before the participant's next treatment visit, the participant should be re-consented with the revised ICF in lieu of the verbal notification process. Refer to the HDFCCC Policy for Obtaining Informed Consent of Potential Patients for Therapeutic and Non-Therapeutic Oncology Clinical Trials.

References

FDA Guidelines

- 21 CFR 50.25 (b) (5) and 45 CFR 46.116(b) (5)

HDFCCC Policies

- HDFCCC External Safety Policy
- HDFCCC Policy for Obtaining Informed Consent of Potential

Patients for Therapeutic and Non-Therapeutic Oncology Clinical Trials.

Policy Approval

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

DocuSigned by:
Eric Small
7FCB32D327E3438...

2/8/2024

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

Date

DocuSigned by:
Katie Kelley
7F538467F93949B...

2/8/2024

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

Date

DocuSigned by:
Rahul Aggarwal
F870F084A5CA4CC...

2/8/2024

Rahul Aggarwal, MD
Acting Medical Director, Clinical Research Support Office
Associate Director, Clinical Sciences
Helen Diller Family Comprehensive Cancer Center

Date

DocuSigned by:
Kate Shumate
80D38159E89D41B...

2/8/2024

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

Date

Policy contact:
Andrea Skafel, Clinical Research Support Office Director
andrea.skafel@ucsf.edu; +1 415 502 5805

Clinical Research Policy Revision
Summary of Changes

Policy Title: Policy for Verbal Notification of New High Risk Adverse Events
Version Date: 02/06/2024
Version Number: Revision 2

Section(s)	Summary of Change	Rationale
All	Converted document template to match Form_Clin_Rsch_Policy_Template_Style_Guide_CURRENT, including adding Scope and Background sections	To follow Policy on Clinical Research Policies
All	Changed “high-risk” instances to “high risk”	Consistency
2.0	Adjusted language regarding PI determination	Clarity
3.0	For oral IP, changed deadline of notification from “10 business days” to “before next dispensation for oral agents”.	Align with workflow for infused drugs
3.0, 6.0	Added that participants within 30 days of their last dose should be notified along with on-treatment participants	General best practice, 30 days post treatment participants may still experience AEs
4.0	Clarified re-consent requirements for participants off treatment	References to HDFCCC consent policy for re-consent workflows
5.0	Added statement regarding withdrawal documentation	Clarify withdrawal process resolution

DocuSign

Certificate Of Completion

Envelope Id: 29353D5CB1BC4671ADFB6181C0BEA72D
Status: Completed
Subject: Complete with DocuSign: Policy_for_Verbal_Notif_of_New_High_Risk_FINAL_revision 2_2024FEB06_cle...
Source Envelope:
Document Pages: 6
Signatures: 4
Certificate Pages: 2
Initials: 0
AutoNav: Enabled
EnvelopeId Stamping: Disabled
Time Zone: (UTC-08:00) Pacific Time (US & Canada)

Envelope Originator:
Andrea Skafel
1855 Folsom St
Suite 601
San Francisco, CA 94103
andrea.skafel@ucsf.edu
IP Address: 128.218.42.132

Record Tracking

Status: Original
2/6/2024 10:45:23 AM
Holder: Andrea Skafel
andrea.skafel@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)	DocuSigned by: Eric Small 7FCB32D327E3438... Signature Adoption: Pre-selected Style Using IP Address: 76.126.140.231	Sent: 2/6/2024 10:47:10 AM Viewed: 2/8/2024 7:46:51 AM Signed: 2/8/2024 7:47:05 AM
Electronic Record and Signature Disclosure: Not Offered via DocuSign		
Katherine Shumate kate.shumate@ucsf.edu Chief of Staff, Director of Administration University of California, San Francisco Security Level: Email, Account Authentication (Optional)	DocuSigned by: Kate Shumate 80D38159E89D41B... Signature Adoption: Uploaded Signature Image Using IP Address: 128.218.42.224	Sent: 2/8/2024 7:47:06 AM Viewed: 2/8/2024 10:10:08 AM Signed: 2/8/2024 10:10:21 AM
Electronic Record and Signature Disclosure: Not Offered via DocuSign		
Rahul Aggarwal rahul.aggarwal@ucsf.edu Rahul Aggarwal, MD Professor of Medicine University of California, San Francisco Security Level: Email, Account Authentication (Optional)	DocuSigned by: Rahul Aggarwal E870F084A5CA4CC... Signature Adoption: Pre-selected Style Using IP Address: 128.218.42.93	Sent: 2/8/2024 10:10:22 AM Viewed: 2/8/2024 10:25:37 AM Signed: 2/8/2024 10:25:43 AM
Electronic Record and Signature Disclosure: Not Offered via DocuSign		
Katie Kelley katie.kelley@ucsf.edu MD University of California, San Francisco Security Level: Email, Account Authentication (Optional)	DocuSigned by: katie kelley 7F538467F93949B... Signature Adoption: Pre-selected Style Using IP Address: 128.218.42.122	Sent: 2/8/2024 10:25:44 AM Viewed: 2/8/2024 11:06:19 AM Signed: 2/8/2024 11:06:33 AM
Electronic Record and Signature Disclosure: Not Offered via DocuSign		

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	2/6/2024 10:47:10 AM
Certified Delivered	Security Checked	2/8/2024 11:06:19 AM
Signing Complete	Security Checked	2/8/2024 11:06:33 AM
Completed	Security Checked	2/8/2024 11:06:33 AM

Payment Events	Status	Timestamps