UCSF Helen Diller Family Comprehensive Cancer Center

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

Policy for Clinical Trial SAE Reporting Outside of Business Hours

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Purpose

This policy defines the process for ensuring timely reporting of Serious Adverse Events (SAEs) occurring under externally sponsored clinical trials conducted at the Helen Diller Family Comprehensive Cancer Center (HDFCCC).

Scope

This policy applies to all interventional clinical trials conducted at the HDFCCC in which the clinical trial protocol mandates expedited (within 72 hours) SAE reporting to an external sponsor.

Definitions

Business hours – 9:00am - 5:00pm Pacific Time, Mondays through Fridays, except holidays.

Background

FDA Investigational New Drug applications (INDs) and Investigational Device Exemptions (IDEs) require trial sponsors report serious human safety-related events and unanticipated problems to the FDA expeditiously. To ensure sponsors can meet FDA deadlines, clinical research protocols include expectations on the speed at which sites or investigators must report SAEs to the sponsor. At the HDFCCC, clinical research support staff (i.e., clinical research coordinators (CRCs)) are not available to assist with reporting outside of business hours.

Procedures

1.0 Initial Reports

In the event that a Principal Investigator (PI) 1) becomes aware of an SAE outside of business hours and 2) the discovery timing is such that a full submission with the help of clinical research support staff is impractical, the PI will contact the trial's medical monitor or primary study contact via email or phone, as per protocol specific reporting timelines (or 1 calendar day, whichever is longer) to alert the sponsor of the event. The message will contain de-identified safety details known to the investigator at the time of the report, including: specified subject (study assigned participant ID), a suspected drug (if any), the reporting source (if not the investigator themself), SAE terms(s), date of SAE onsite, date of PI awareness, and a brief clinical description of the event, including a preliminary assessment of whether a reasonable possibility exists that the drug caused the event.

If the event is communicated via phone, the investigator should follow up the phone call with an email to document the phone call's occurrence. Within one business day or the time allowed in the protocol, whichever is longer, the study team will file a full report per the protocol and reporting portal requirements.

In the event the PI is unavailable (e.g. vacation), prior to their absence, they may delegate reporting to an appropriate sub-investigator. The delegated sub-investigator should have access to the appropriate sponsor contact information as described above.

2.0 Follow-Up Reports

If a clinical trial investigator receives new information pertaining to a previously submitted SAE report (e.g., event end date) outside of business hours, the investigator and study team should make a concerted effort to report the new information within 10 business days of awareness.

If the new information qualifies as a new SAE (as per protocol) e.g., severity or seriousness of event changes, the procedures in section 1.0 apply.

Policy Exemptions

None

References

21 CFR 312 - INDs
21 CFR 812 - IDEs
UCSF Holiday Schedule

Policy Approval

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

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6/11/2024

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Associate Director, Clinical Sciences
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Date

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6/11/2024

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DocuSign

Certificate Of Completion

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Source Envelope:
Document Pages: 3
Signatures: 3
Certificate Pages: 2
Initials: 0
AutoNav: Enabled
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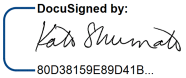
Katherine Shumate kate.shumate@ucsf.edu Chief of Staff, Director of Administration University of California, San Francisco Security Level: Email, Account Authentication (Optional)	DocuSigned by:  80D38159E89D41B... Signature Adoption: Uploaded Signature Image Using IP Address: 128.218.42.65	Sent: 6/11/2024 9:50:32 AM Viewed: 6/11/2024 12:27:17 PM Signed: 6/11/2024 12:27:25 PM
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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:  E870F084A5CA4CC... Signature Adoption: Pre-selected Style Using IP Address: 64.54.15.151	Sent: 6/11/2024 9:50:33 AM Viewed: 6/11/2024 9:51:26 AM Signed: 6/11/2024 9:51:31 AM
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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
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Certified Delivered	Security Checked	6/11/2024 9:51:26 AM
Signing Complete	Security Checked	6/11/2024 9:51:31 AM
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Payment Events	Status	Timestamps