Title: Reporting Serious Adverse Events

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REVISION HISTORY (most recent first)

Version	Effective Date	Summary of Changes
2.0	SEP-10-2020	Clarify in-patient hospitalization, update DCP Regulatory Contractor phone number, clarify query response submittal, update contact information in Appendix I.
1.0	AUG-17-2020	Original version of document.

1. INTRODUCTION AND PURPOSE

Investigators, Co-Investigators, Site Coordinators, and designees at Cancer Prevention Clinical Trials Network (CP-CTNet) Lead Academic Organizations (LAOs) and Affiliated Organizations (AOs) are responsible for the proper and timely reporting of all serious adverse events (SAEs) that occur during the conduct of a study.

The enrolling site (LAO or AO) where the SAE occurred is responsible for reporting the SAE to the Division of Cancer Prevention (DCP) Medical Monitor and DCP's Regulatory Contractor by phone or email, and on the DCP Serious Adverse Event Report Form. If the SAE occurred at an AO, the AO must also report the event to the LAO. Reporting to the FDA and/or pharmaceutical sponsor will be based on protocol requirements.

An SAE is defined by the Code of Federal Regulations (CFR) as any untoward medical occurrence that at any dose has one or more of the following outcomes:

1. Death
2. A life-threatening event.

   Per Food and Drug Administration (FDA) regulations, a life-threatening event places the participant at immediate risk of death. It does not include an event that, had it occurred in a more severe form, might have caused death.
3. Inpatient hospitalization or prolongation of existing hospitalization.

   FDA does not define what constitutes inpatient hospitalization. The National Cancer Institute (NCI) DCP uses admission or stay (including emergency room) equal to or greater than 24 hours as the definition of hospitalization. Exceptions are hospitalization for treatment of a pre-existing condition (unless the condition increased in severity on study), outpatient surgery, planned/elective procedures, and procedures described in the protocol (e.g., pharmacokinetic sampling, surgery). These events ***should not*** be reported by the investigator/co-investigator on the DCP Serious Adverse Event Report Form even if the hospital stay is of greater than 24 hours duration.

   In contrast, an event occurring during any hospitalization, even during protocol defined procedures, that prolongs the hospitalization or an event with another serious outcome should be considered an SAE and reported by the investigator/co-investigator on the DCP Serious Adverse Event Report Form. The Division of Cancer Prevention (DCP) Medical Monitor and DCP's Regulatory Contractor should also be notified by phone or email.
4. A persistent or significant incapacity or substantial disruption of the ability to perform normal life functions
5. A congenital anomaly or birth defect
6. Important medical events that may not be immediately life-threatening or result in death or hospitalization should also be considered serious when, based upon appropriate medical judgment, they may jeopardize the participant or may require intervention to prevent one of the other outcomes listed above.

   FDA's examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

2. SCOPE

This document details the responsibilities of the LAO and AO Investigators, Co-Investigators, Site Coordinators, and designees regarding the reporting of SAEs, including initial reporting, follow-up, and documentation.

3. RESPONSIBILITIES FOR REPORTING SAES

Investigators, Co-Investigators, Site Coordinators, and designees at each enrolling site will report SAEs as follows:

3.1. Contact the assigned DCP Medical Monitor (phone and email as listed in the protocol) and DCP's Regulatory Contractor, by phone (650-691-4400 x133) or email (safety@ccsainc.com) within 24 hours of knowledge of an SAE, and communicate the following information:

a. Participant ID

b. Date and time of SAE onset;

c. Date and time the site was notified about the SAE by the study participant or other person(s);

d. Name of the person who is reporting the SAE;

e. Call back phone number;

f. Affiliation/institution conducting the study;

g. DCP protocol number;

h. Title of protocol; and,

i. Description of SAE, including attribution to the investigational agent.

3.2. Email a copy of the completed DCP Serious Adverse Event Report Form to the DCP Medical Monitor (email as listed in the protocol) and to the DCP Regulatory Contractor (safety@ccsainc.com) within 48 hours of learning of the event. The information must be entered onto the Word form; the form should then be signed with a wet ink signature, scanned, and emailed. For guidance or assistance, the DCP Regulatory Contractor may also be reached by phone at 650-691-4400 x133 during regular business hours (PT).

a. Reference the SAE Reporting Form Instructions for assistance in completing the DCP Serious Adverse Event Report Form.

b. Ensure that an Investigator or Co-Investigator for the site where the SAE occurred signs the form.

c. If the SAE occurred at an AO, also forward the completed form to the LAO Site Coordinator.

3.3. Comply with all institutional requirements and all Central Institutional Review Board (CIRB) requirements related to reporting of SAEs.

3.4. Respond to any queries from the DCP Regulatory Contractor.

3.5. When applicable (e.g., revised information, new follow-up information), complete follow-up reports using the previously submitted DCP Serious Adverse Event Report Form as soon as additional information is available. The Investigator or Co-Investigator should also sign and date each follow-up report.

3.6. Send follow-up reports to the following:

a. DCP Medical Monitor;

b. DCP Regulatory Contractor; and,

c. LAO Site Coordinator, if the SAE occurred at an AO.

3.7. Comply with the instructions listed in the protocol regarding the length of time for follow-up of an SAE.

4. DOCUMENTATION REQUIREMENTS:

4.1. Each enrolling site (LAO and AO) will retain in their study files a copy of the DCP Serious Adverse Event Report Form, supporting documentation, and communications related to the reporting of the SAE. All participant identifiers should be redacted from copies of the supporting documentation.

4.2. The LAO Site Coordinators and/or designees will retain in the LAO study files a copy of each DCP Serious Adverse Event Report Form and supporting documentation from all AO enrolling sites.

5. ADDITIONAL INFORMATION:

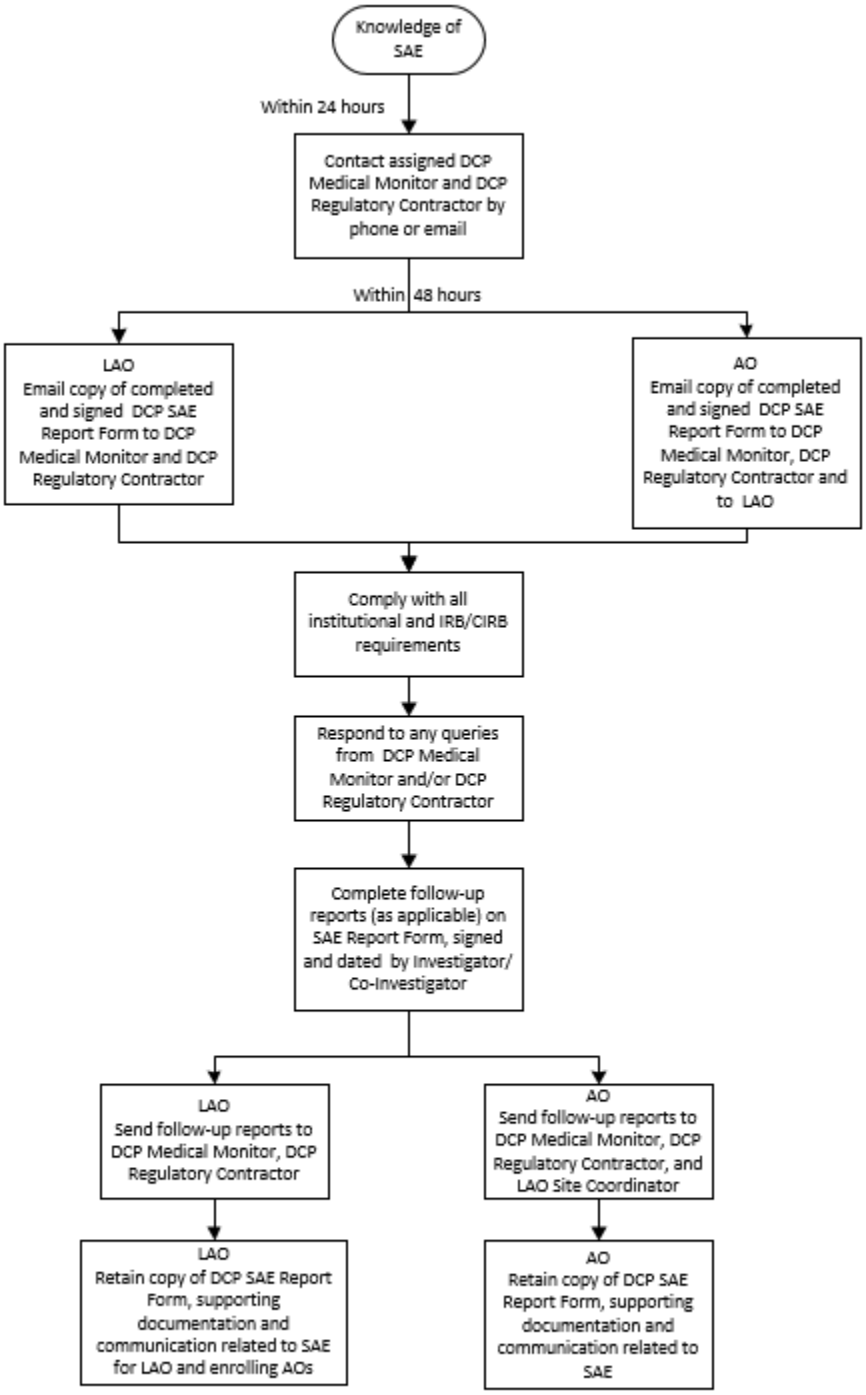
5.1. Questions related to the reporting of SAEs may be directed to the DCP Regulatory Contractor at safety@ccsainc.com

5.2. Refer to the **CP-CTNet Acronym List** to see the description of commonly used acronyms in this SOP.

Please send questions and comments to DataManagement_CP-CTNet@frontierscience.org

- ## REFERENCES
  - None
- ## APPENDICES
  - Appendix I – Reporting Serious Adverse Events

Appendix I
Reporting Serious Adverse Events



Contact Information:
DCP Medical Monitor: Refer to the phone number and email address as listed in the protocol
DCP Regulatory Contractor: phone (650-691-4400 x133), e-mail (safety@ccsainc.com)

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