

## CCR SAE Report Form: Instructions

### General Instructions:

1. Make sure all questions have been answered and all highlighted areas have been addressed prior to submission to CCRSafety@mail.nih.gov.
2. Avoid copying and pasting from prior SAE Report Forms to increase accuracy.
3. Assure any submitted supplemental reports and medical records are redacted to avoid a breach in participant privacy.
4. Make all attempts to review the SAE Report Form with PI or PI designee prior to submission to CCR Safety.
5. When preparing a follow-up report, use the initial report and revise as needed.
6. If a new event occurs during a previously reported hospitalization, only report that event if it is an SAE, i.e. it prolonged the hospitalization or resulted in patient's death. In this case, the new event should be submitted on a new SAE report form as an initial event.

### Report Information:

1. Date of this Report = Date of Submission to CCR Safety
2. Report Type must be indicated. Follow up reports should be numbered in sequential order and should correspond with the Follow Up # being added under Description of Events.
3. If you select "Yes" under "Is a follow-report anticipated?" note that you may receive a future query from the pharmaceutical company requesting a follow up if you fail to submit one.

### IND Agents:

1. **All** products that are part of the IND regimen should be included. This includes all investigational drugs as well as any commercial drugs being used to test the research hypothesis.

### SAE List:

1. Report only the event(s) that make the AE a serious event. Think of what event(s) resulted in the patient's hospitalization/prolongation of hospitalization/death/life-threatening event, etc.
2. Be sure to use a valid CTCAE term according to the CTCAE version indicated in the protocol.
3. Regarding attribution, it is important to assign an attribution for the event(s) to every IND agent(s). For example, SAE #1: related to IND agents # 1, 2, 3; not related to IND agent #4.
4. Refrain from attributing an event to "research". Instead, specify the research agent by name to which you are attributing the event.

### Description of Events:

1. Start with Initial Description of event.
2. When adding a Follow Up Description of Events for a follow-up report, assure the date of the Follow Up corresponds with the date of this report and the date of submission to CCR Safety.
3. Do not make any changes to previously reported description of events. Click on the + sign that allows you to add Follow-up # 1, 2, 3, etc.
4. Make all updates to previously reported events in the new Follow Up Description of Events.
5. Changes to event terms, grades and attributions should be specified in the Description of Events and should also be updated in the SAE List on page 1.