

OnCore System Work Instruction Document

Serious Adverse Events (SAE) For Research Nurses

Prepared For: OnCore Version 2020R2

Revision Number: 4

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The URL for OnCore is <https://OnCore.ynhh.org>

For more information about OnCore please visit the project website at <http://OnCore.yale.edu>



Yale Center for
Clinical Investigation

OnCore[®]
Enterprise-Class
Clinical & Translational
Research Software

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SAE Tab

From the home screen select the **Subjects** horizontal tab and then from the drop down select the **CRA Console**.

Select Protocol: Start typing the protocol and the drop down will automatically filter, when the correct protocol appears click on the hyperlink.

Select Subject: Start typing the subject name or MRN and the drop down will automatically filter, when the correct subject appears click on the hyperlink.

Or

Subject MRN: Select the MRN hyperlink for the correct subject.

★ Subject Console ?

Protocol No.: 1602017270 Protocol Status: OPEN TO ACCRUAL Subject Status: ON TREATMENT
MRN: MR123456 Subject Name: Sally Test Sequence No.:

Switch Subject No Records Found

Type here to search

Summary
Demographics
Consent
Eligibility
On Study
Treatment
Follow-Up
SAEs

New

4. **SAEs:** Click this vertical tab to go to the screen for Serious Adverse Events

5. **New:** Click this button in order to add a new SAE and the SAE Table will open in the window.

Subject SAE Update: Status: Not Complete

Event Date* (MM/DD/YYYY) Event End Date (MM/DD/YYYY) Reported Date* (MM/DD/YYYY) Reported By
Death Date Death Occurred Did the SAE occur at your site or at a site for which the PI is responsible?
Event Narrative
Treating Physician Comments
PI Comments
Protocol Attribution Outcome* Consent Form Change Required
SAE Classifications Multi-Select
Report to IRB?

6. **Event Date:** Enter the date the SAE started.

7. **Event End Date:** Enter the date the SAE ended.

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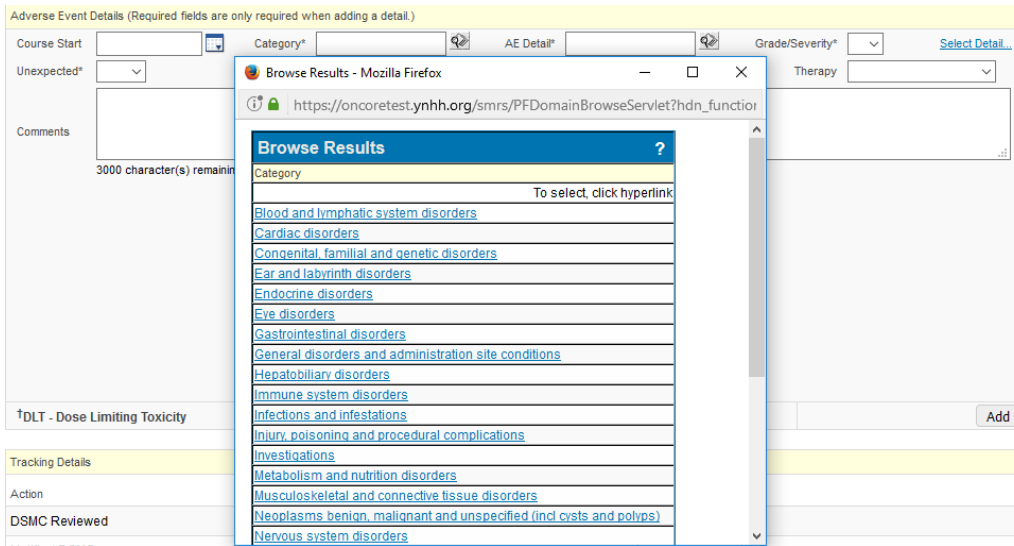
8. **Reported Date:** Enter the date the SAE was reported to the study staff.
9. **Reported By:** Enter the first and last name of the person who reported the SAE.
10. **Death Date:** If the subject died related to this SAE, enter the date of death.
11. **Death Occurred:** From the drop down indicate how soon after the SAE that the subject died.
12. **Did the SAE occur at your site or at a site for which the PI is responsible?:** Check the checkbox if appropriate.
13. **Event Narrative:** Enter text to record the event and any intervention taken. This should include subject initials, age, sex, height, weight, enrollment date, treatment name and dosage, date SAE started, names of concomitant medications and their start dates, treatment for SAE including dosage, current status (hospitalized, recovering etc.)
14. **Treating Physician Comments:** Enter text in this field for the treating physician's comments. This should include relation of SAE to study medication, status of patient, recovery information, follow-up timeline, and a plan for treatment going forward.
15. **PI Comments:** Enter text in this field for the PI's comments.
16. **Protocol Attribution:** From the drop down select the protocol attribution.
17. **Outcome:** From the drop down select the SAE outcome.
18. **Consent Form Change Required:** Check the box if the consent form should be changed due to this SAE.

SAE Classifications		
Report to IRB?	SAE Classifications	
	<u>A life-threatening occurrence</u>	
Adverse Event Det	<u>A persistent or significant disability/incapacity</u>	
Course Start	<u>Another experience suggesting significant hazard, contraindication, side effect, or precaution</u>	<input type="checkbox"/> Select Detail...
Unexpected*	<u>Death/Suicide</u>	<input type="checkbox"/>
	<u>Hospitalization</u>	<input type="checkbox"/>
Comments	<u>Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition</u>	
	<u>Loss of confidentiality that results in criminal or civil liability for participation or damage to financial standing, employability, insurability or reputation of the participant</u>	

19. **Select:** Click this button to add the SAE classification and a drop down will appear.
20. **Select?:** Check all applicable classifications.
21. **Add:** Once all applicable boxes have been added click out of drop down.

Toxicity Table

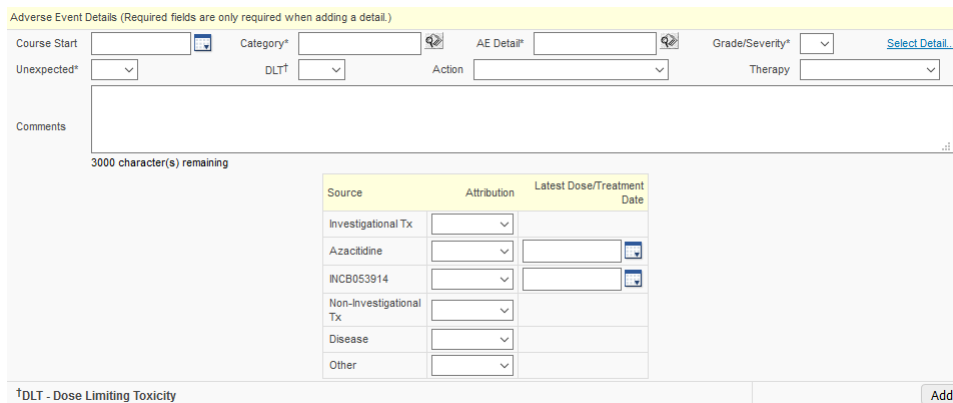
22. **Course Start:** Enter the date the subject started the treatment cycle.



23. **Select Toxicity:** Click this hyperlink to search all CTCAE toxicities from a pop up window.

24. **Select Item from the List below:** Begin typing the SAE CTCAE toxicity and the table will filter. Click on the appropriate CTCAE when it appears

25. **Select:** Click this button when you have the appropriate toxicity and you will be brought back to the Toxicity Table where the details will be pre-populated.



26. **Category:** Click the browse button and click the hyperlink for the appropriate toxicity group.

27. **Toxicity:** Click the browse box and click the hyperlink for the appropriate toxicity.

28. **Grade:** Select the toxicity grade from the dropdown list.

29. **Unexpected:** Select Yes if the toxicity has previously been reported for this treatment. Select No if it has not yet been reported for this treatment.

- a. For example if a lung patient goes to the hospital for shortness of breath this is related to the illness and not related to the treatment so this should not be entered as unexpected.

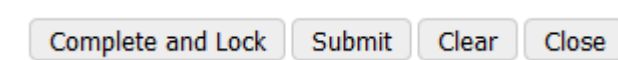
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30. **DLT:** Select Yes if this is a dose limiting toxicity, No, or leave empty.
31. **Action:** From the drop down select the appropriate action taken.
32. **Therapy:** From the drop down select the therapy provided to the patient to treat the toxicity.
33. **Comments:** Enter any extra details about the toxicity and plan for treatment.
34. **Source:** For each category below select an attribution from the drop down.
35. **Attribution:** From the drop down select the appropriate attribution for that toxicity.
36. **Add:** If you need to add more than one toxicity for the SAE click this button.

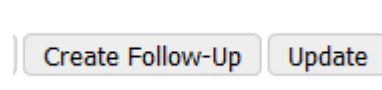
Tracking Details

Tracking Details	
Action	Action Date
DSMC Reviewed	<input type="text"/> [v]
Notified DSMC	<input type="text"/> [v]
Notified FDA	<input type="text"/> [v]
Notified IRB	<input type="text"/> [v]
Notified Regulatory Coordinator	<input type="text"/> [v]
Notified Sponsor	<input type="text"/> [v]
Reviewed By Regulatory Coordinator	<input type="text"/> [v]
Team Reviewed	<input type="text"/> [v]

37. **Action:** For each of the actions described enter an action date as they become available during the process.
38. **Action Date:** Enter the date the related action took place.



39. **Submit:** Click this button once all data has been entered correctly for the SAE
40. **Complete and Lock:** Click this button if it is appropriate to lock the SAE to future changes/edits.



41. **Create Follow Up:** This button will appear once the SAE has been completed and locked. Use this to add any additional details related to the SAE.