YaleNewHavenHealth Yale SCHOOL OF MEDICINE

OnCore System Work Instruction Document

Protocol Deviation Reporting:
For Research Nurses and Data Managers

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

Introduction

A clinical protocol that meets scientific and ethical standards is a fundamental requirement of any clinical investigation. In order to ensure the safety and welfare of study participants and the scientific validity of the study, the approved protocol must be conducted as written. However, there are occasions when inadvertent omission or delay in obtaining a particular study evaluation or measurement has no potential effect on patient safety or the integrity of the entire study. The purpose of these work instructions is to provide instructions on data to be gathered should the deviation require reporting to other bodies, such as a drug company sponsor.

Minor Noncompliance

Any behavior, action or omission in the conduct or oversight of research involving human subjects that deviates from the approved research plan, federal regulations or institutional policies but, because of its nature, research project or subject population, does not:

1. place, or have the potential to place, participants and others at greater risk than previously anticipated;
2. have a substantive effect on the value of the data collected; and
3. result from willful or knowing misconduct on the part of the investigator(s) or study staff.

Examples of minor noncompliance may include, when such noncompliance does not create additional risks to subjects:

1. Changing study personnel without notifying the IRB;
2. Shortening the duration between planned study visits;
3. Implementing minor wording changes in study questionnaires without first obtaining IRB approval;
4. Routine lab missed at scheduled visit and re-drawn later.

https://your.yale.edu/policies-procedures/policies/700-hrpp-policy-700-noncompliance-suspension-and-termination

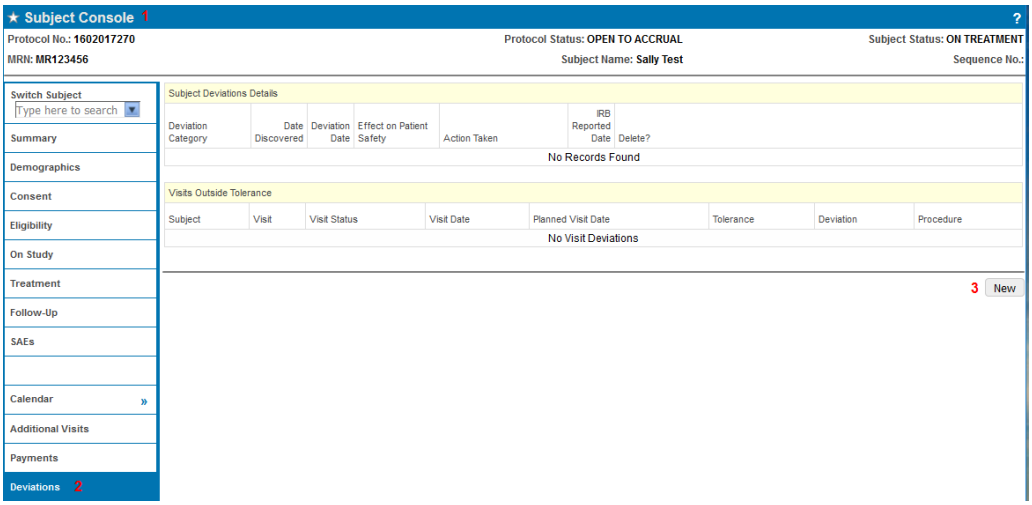
Reporting Deviations to the IRB

If you answer yes to any of the following questions you need to report the deviation to the IRB.

1. Does the deviation affect or have the potential to affect the rights and welfare of the participants or others, or compromise the integrity of the research?
2. Did the deviation put participants at greater risk of harm (including physical, psychological, economic or social harm) than was previously known or decrease benefits of the research?
3. Is the deviation one that is minor (i.e., does not affect the rights and welfare of subjects or increase risk or decrease benefits) but is similar to one that has occurred at the site on previous occasions?

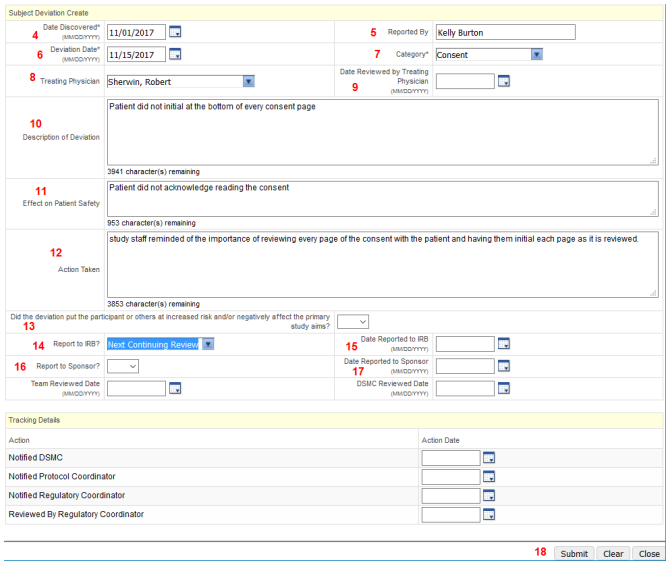
https://your.yale.edu/policies-procedures/procedures/700-pr-1-reporting-noncompliance-and-protocol-deviations-irb

Deviations Tab:



1. From the **CRA Console** select the protocol and then the subject(*not shown on this screen shot)*. Or if you are already in the **Subject Console**
2. Click the **Deviations** vertical tab.
3. Then click **New** on the lower right**.**

Subject Deviation Update



4. **Date Discovered:** Enter the date the clinician or member of his/her research team became aware of the deviation. If multiple dates are applicable select the earliest date. The current date will pre-populate but this can be changed.
5. **Reported By:** Enter the first and last name of the person who is reporting the deviation.
6. **Deviation Date:** Enter the date when the deviation happened. If multiple dates are applicable select the earliest date.
7. **Category:** From the drop down select the appropriate deviation categorization. Select the most logical category based on deviation/noncompliance type for drop down.
8. **Treating Physician:** Begin typing the name of the physician and the drop down will automatically filter, click on the hyperlink when the appropriate name appears.

9. **Date reviewed by treating physician:** Enter the date the treating physician reviewed the deviation details.
10. **Description of Deviation:** Enter a brief description of the deviation.
11. **Effect on Patient Safety:** Enter information about the deviation's effect on the patient safety.
12. **Action Taken:** Enter the action taken due to the deviation and any action to prevent recurrence.
13. **Did the deviation put the participant or others at increased risk and/or negatively affectthe primary study aims?:** Check this box as applicable.
14. **Report to the IRB?:** From the drop down select when the deviation needs to be reported.
15. **Date Reported to IRB:** Enter the date the deviation was reported.
16. **Report to sponsor?:** Check the box if the deviation needs to be reported to the sponsor.
17. **Date Reported to Sponsor:** Enter the date the deviation was reported.
18. **Submit:** Click this button once all of the details have been entered correctly.

19. **PI Report Format:** Once you have completed the deviation entry you can select a report type from the "PI Report Format"
20. **PI Report:** Click this button to download the report.
    Subject Deviation PDF: Click this button to view the details.