

RECORD SUBJECT DEVIATIONS

Description: OnCore provides a place for study teams to record, display, and update subject deviations that might need to be reported to the IRB and/or the sponsor.

Audience: Study teams who wish to track their deviations in OnCore.

SUBJECT DEVIATIONS

A subject deviation from the approved protocol procedures is recorded in the **Deviations** tab of the **Subject Console**.

Note: **Visits Outside Tolerance** deviations are automatically created when a subject visit is occurred outside the tolerance in the study calendar.

Create a Subject Deviation

1. Navigate to **Menu > Subjects > Subject Console**.
2. [Find your Subject](#), then select the **Deviations** vertical tab.

The screenshot shows the 'Subject Console' for Protocol No. OCR16260 and Subject MRN: 34397. The subject name is Albert Gator and the status is OFF STUDY. The left sidebar has the 'Deviations' tab selected. The main content area shows 'Subject Deviations Details' with a table that currently has 'No Records Found'. Below that, 'Visits Outside Tolerance' also shows 'No Visit Deviations'. A 'New' button is highlighted in a red box in the bottom right corner of the main content area.

3. Click the **[New]** button. The *Subject Deviation Create* form opens.
4. Enter the required fields: **Date Discovered**, **Deviation Date**, and **Category**.

The screenshot shows the 'Subject Deviation Create' form. The 'Date Discovered*' field is set to 04/05/2020. The 'Deviation Date*' field is empty. The 'Category*' field is set to 'Type here to search'. The 'Reported By' field is set to Edythe Zettler. The 'Treating Physician' field is set to 'Type here to search'. The 'Date Reviewed by Treating Physician' field is empty.

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5. Enter any other appropriate details as desired.
6. Click **[Submit]** and **[Close]**.

Display and Update ALL Subject Deviations for a Protocol

1. Navigate to **Menu > Protocols > PC Console**.
2. [Find your study](#) using the **Select Protocol** search field.
3. Using the vertical menu bar, navigate to **Deviations > Subject Deviations**.
4. If you only want to see deviations that do not have an **IRB Reported Date** entered, click the checkbox next to **Show Only Unreported Deviations**.

Study_Site	Subject MRN	Subject Name	Deviation Category	Deviation Description	Date Discovered	Deviation Date	Effect on Patient Safety	Action Taken	Role Responsible for Action Taken	Has the integrity or validity of the data been compromised?	Was an IRB waiver granted?	IRB Reported Date	Select
UF Gainesville	34397	Albert E Gator	Scheduled Test		04/05/2020	4/01/2020							<input type="checkbox"/>

5. If you only need to update the **IRB Reported Date** on one or more deviations, you do not have to open each record – simply:
 - a. Click the **Select** checkbox next to each deviation that was reported to the IRB on the same date.
 - b. Enter the report date into the **Update Selected IRB Reported Dates**.
 - c. Click **[Update]**.
 - d. Repeat as needed for each report date.
6. If you need to display or update the details of an existing deviation, select the deviation [blue hyperlink](#) in the **Date Discovered** column.
7. Click **[Update]** at the bottom of the page.
8. Enter any appropriate details as desired.
9. Click **[Submit]** and **[Close]**.

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Display and Update A Single Subject's Existing Deviations

1. Navigate to **Menu > Subjects > Subject Console**.
2. [Find your Subject](#), then select the **Deviations** vertical tab.

★ Subject Console ?

Protocol No.: OCR16260 Protocol Status: IRB STUDY CLOSURE Subject Status: OFF STUDY
Subject MRN: 34397 Subject Name: Albert Gator Sequence No.: 10

Switch Subject
Type here to search

Summary
Demographics
Consent
Eligibility
On Study
Treatment
Follow-Up
SAEs
Calendar »
Additional Visits
Payments
Deviations

Subject Deviations Details

Deviation Category	Deviation Description	Date Discovered	Deviations Date	Effect on Patient Safety	Action Taken	Role Responsible for Action Taken	Has the integrity or validity of the data been compromised?	Was an IRB waiver granted?	IRB Reported Date	Delete?
Scheduled Test		04/05/2020	04/01/2020							Delete

Visits Outside Tolerance

Subject	Visit	Visit Status	Visit Date	Planned Visit Date	Tolerance	Deviation	Procedure
No Visit Deviations							

New

3. To display or update the details of an existing deviation, select the deviation [blue hyperlink](#) in the **Deviations Date** column.
4. Click **[Update]** at the bottom of the page.
5. Enter any appropriate details as desired.
6. Click **[Submit]** and **[Close]**.

*Note: Single subject deviations can also be displayed via **CRA Console > Deviations**, but they cannot be updated from the CRA Console.*

For information about recording protocol deviations, see [Record Protocol Deviations](#).