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

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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

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.

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].
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.

3. To display or update the details of an existing deviation, select the deviation [blue hyperlink](#) in the **Deviation 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**.