

Subject Deviations

A deviation is a variance from the approved Protocol procedures. Deviations are entered at the Subject level via the **Subject Console → Deviations** tab.

1. If you are on the Subject Console, click the **Deviations** vertical tab. (If you are not on the Subject Console, go to the Subjects → CRA Console, enter your protocol number, and select your subject from the Accrual vertical tab. Then click the Deviations tab.)

The top table on the page shows the subject's deviations. The bottom table shows any visits with a visit date outside of the planned date's tolerance. This table is for informational purposes and you can use it as a guide for entering deviations if needed.

2. Click the **New** button to create a Deviation.

The **Date Discovered** and **Reported By** fields default to the current date and user, but may be changed. When entering Deviation data, the required fields are marked with an asterisk.

3. Enter the following:

Date Discovered: *keep the default (the current day)*

Reported By: *keep the default (your user name)*

Deviation Date: 06/21/2011

Category: Treatment

Description of Deviation: Missed a procedure on a visit

4. Click the **Submit** button to create the Deviation.

Other information may be entered to record when it should be reported to IRB, the date it was reported, and the date it was reported to the sponsor.

5. Click the **Deviations** vertical tab to see the updated display.

The Deviation has a Delete hyperlink to the right side for removing those entered in error.