

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

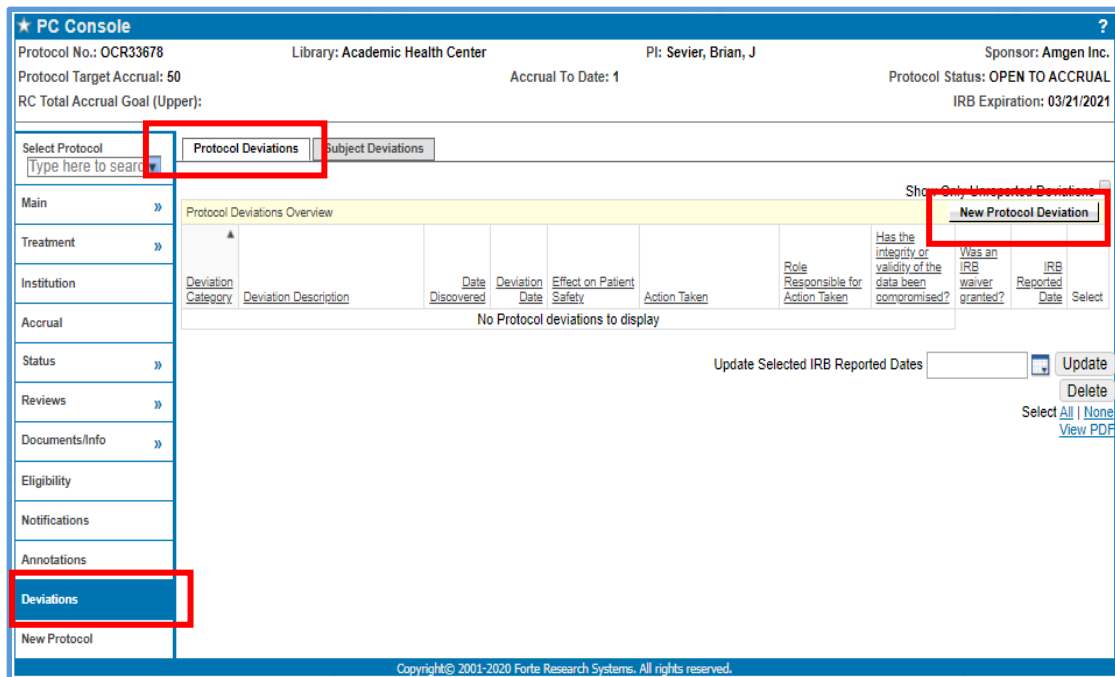
Audience: Study teams who wish to track their deviations in OnCore.

PROTOCOL DEVIATIONS

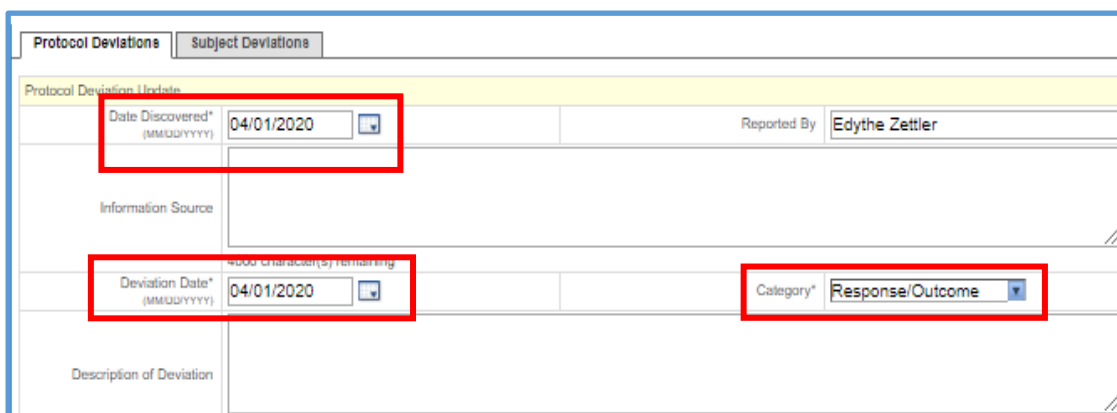
Protocol deviations are unplanned incidents of non-compliance with the study protocol.

Create a Protocol Deviation

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 > Protocol Deviations**.



4. Click on the **[New Protocol Deviation]** button. The *Protocol Deviation Update* form opens.
5. Enter the required fields: **Date Discovered**, **Deviation Date**, and **Category**.



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

Display and Update Protocol Deviations

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 > Protocol 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**.

★ PC Console

Protocol No.: OCR33678 Library: Academic Health Center PI: Sevier, Brian, J Sponsor: Amgen Inc.
Protocol Target Accrual: 50 Accrual To Date: 1 Protocol Status: OPEN TO ACCRUAL
RC Total Accrual Goal (Upper): IRB Expiration: 03/21/2021

Select Protocol Protocol Deviations Subject Deviations

Show Only Unreported Deviations

Protocol Deviations Overview

| 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 |
|---------------------|-----------------------|----------------------------|----------------|--------------------------|--------------|-----------------------------------|---|----------------------------|-------------------|--------------------------|
| Scheduled Test | | 04/02/2020 | 4/02/2020 | | | | | | | <input type="checkbox"/> |
| Specimen processing | | 04/03/2020 | 4/03/2020 | | | | | | | <input type="checkbox"/> |

Update Selected IRB Reported Dates Update

Select All | None View PDF

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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:
 - Click the **Select** checkbox next to each deviation that was reported to the IRB on the same date.
 - Enter the report date into the **Update Selected IRB Reported Dates**.
 - Click **[Update]**.
 - 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]**.

For information about recording subject deviations, see [Record Subject Deviations](#).