**RECORD PROTOCOL DEVIATIONS**

**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**.

![Image of OnCore interface showing Protocol Deviations option]

5. Enter the required fields: **Date Discovered**, **Deviation Date**, and **Category**.

![Image of Protocol Deviation Update form]

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**.

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**.