**Description:** Study subjects are registered to protocols in OnCore to facilitate subject visit tracking, sponsor invoicing, and enrollment reporting. As the subject progresses through the study, the subject's study status must be updated as applicable.



If a subject signs a study consent but subsequently withdraws consent **PRIOR** to being placed **On Study**, the subject's study status should be updated to **Withdrawn**.

If a subject withdraws consent **AFTER** being placed **On Study**, the subject's status should be updated to <u>Off</u> <u>Study</u> where the "Off Study Reason" can be recorded as "Subject Withdrew".

## UPDATE A SUBJECT'S STATUS TO "WITHDRAWN"

- 1. If you are not already in the subject's record,
  - Navigate to Menu > Subjects > CRA Console
  - Select your protocol
  - In the upper right area of your screen, click the Accrued drop down field and change it to All.
  - Click on the blue hyperlink <u>MRN</u> of your subject.
- 2. Click on the **Consent** vertical tab. *Click* **[Update]** *if needed.*
- 3. In the Other Consent Status section, click on the drop-down menu for the Status field and select Withdrawn.
- 4. Enter the withdrawal date in the **Status Date** field.
- 5. Click [Submit].
- 6. Note that the **Subject Status** field at the right top of the page has been updated to **WITHDRAWN**.
- 10. If this study is in both OnCore and Epic, and as long as you do not have the Epic record open for this patient, the <u>Epic</u> research enrollment status for this patient will now automatically be updated to "Inactive-Withdrawn".



WARNING: When registering a subject or updating a subject status in OnCore, make sure that you do <u>NOT</u> have the corresponding study or patient record open in Epic.

*If the Epic record is open, the subject status will <u>NOT</u> update from OnCore.*