Subject - Status Tracking (Non-Industry Studies)

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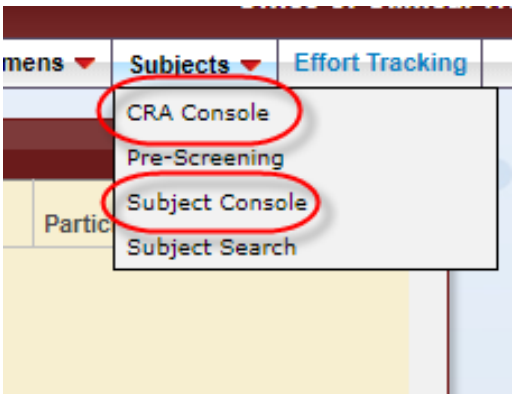
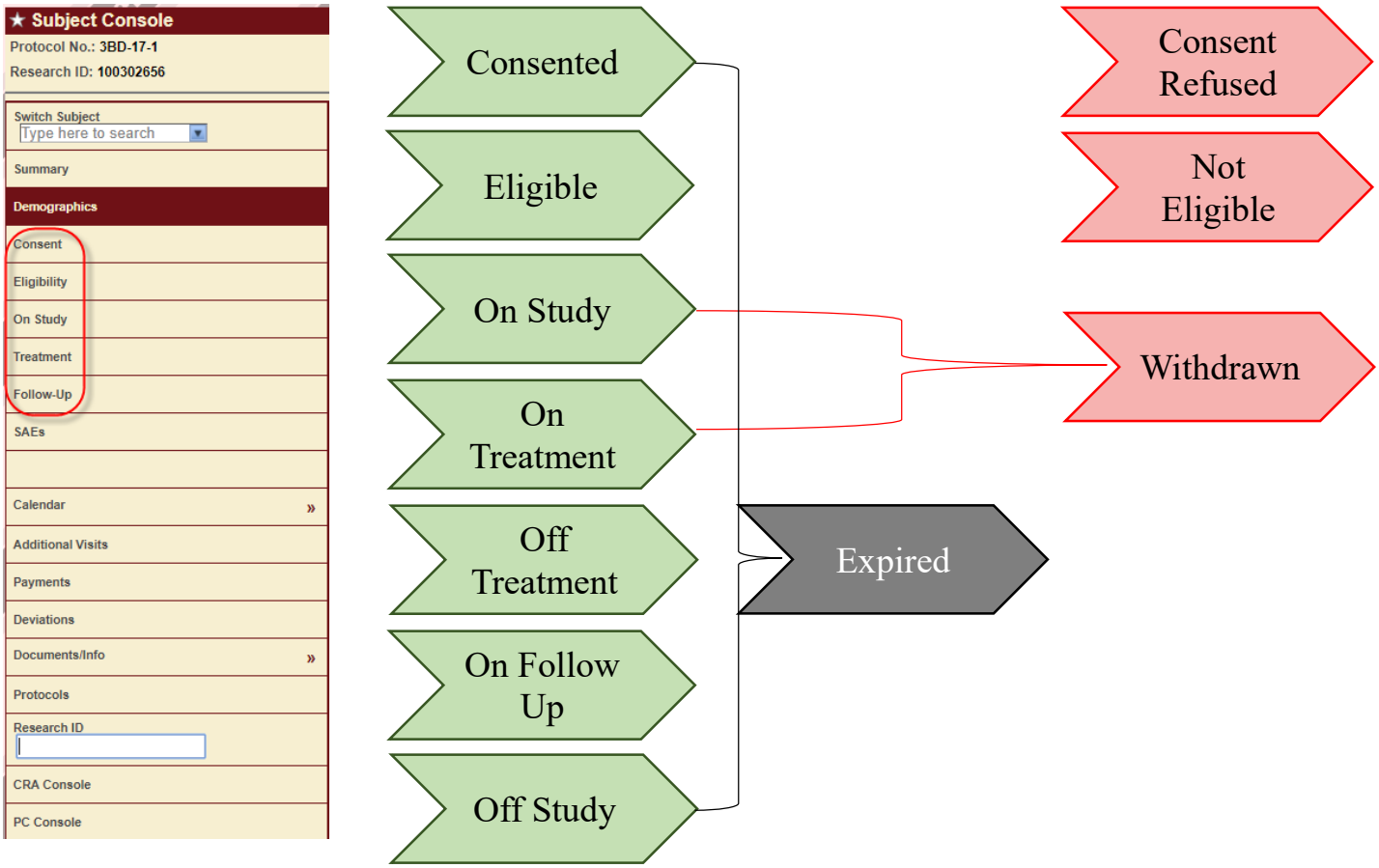
CRA Console – shows all subjects at the protocol level
Subject Console – view individual subject information, such as demographic, consent, eligibility, calendar, etc.



SUBJECT STATUSES

Subject can progress through several statuses during the course of the protocol. The different tabs in the Subject Console allow you to record this status information.



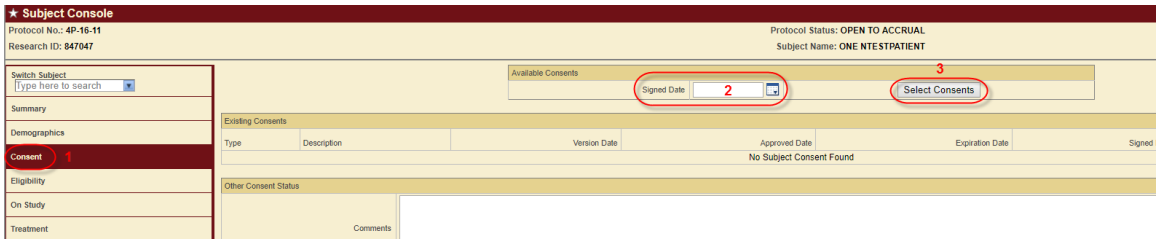
Subject - Status Tracking (Non-Industry Studies)

Consented

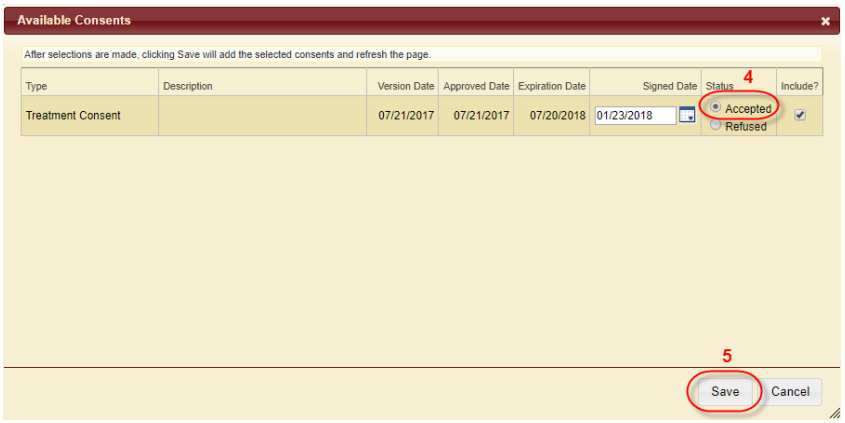
Subject understands and agrees to the details in the consent form.

Steps: (Please make sure to Upload Consent and HIPAA forms in Documents/Info tab)

1. Click on Consent (left tab)
2. Enter the Signed Date
3. Click on Select Consents



4. Select "Accepted"
5. Click Save



6. Displays Consent Information and change Subject Status to "CONSENTED"

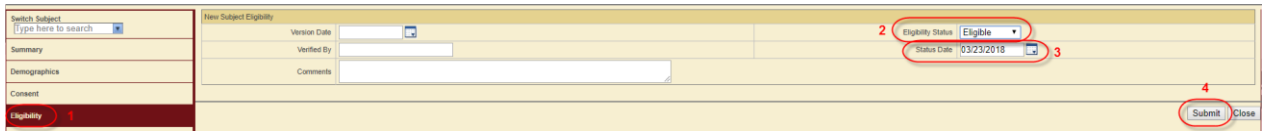
Subject - Status Tracking (Non-Industry Studies)

Eligible

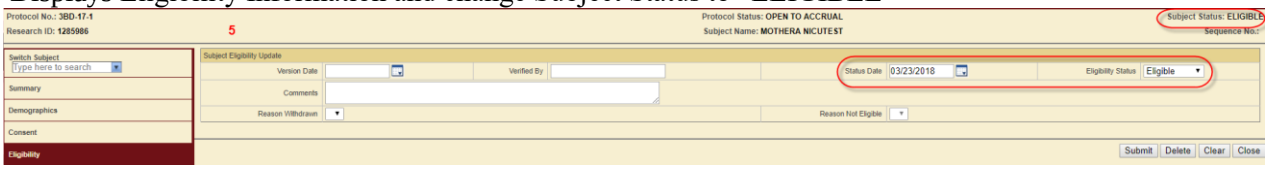
Subject has been evaluated and meets all criteria

Steps:

1. Click on Eligibility (left tab)
2. Select Eligibility Status from the drop down (Eligible)
3. Enter Status Date
4. Click Submit



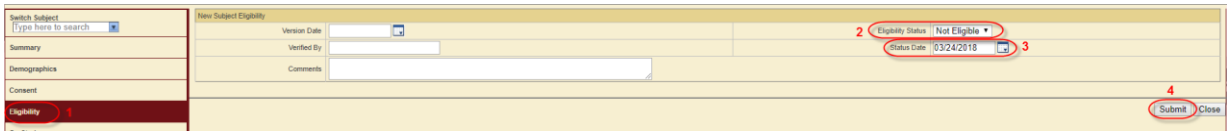
5. Displays Eligibility Information and change Subject Status to "ELIGIBLE"



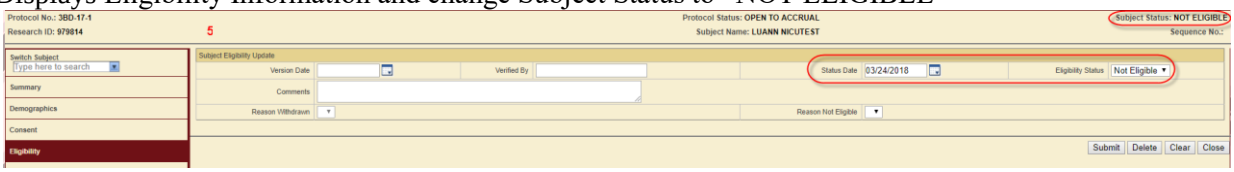
Not Eligible

Steps:

1. Click on Eligibility (left tab)
2. Select Eligibility Status from the drop down (Not Eligible)
3. Enter Status Date
4. Click Submit



5. Displays Eligibility Information and change Subject Status to "NOT ELIGIBLE"



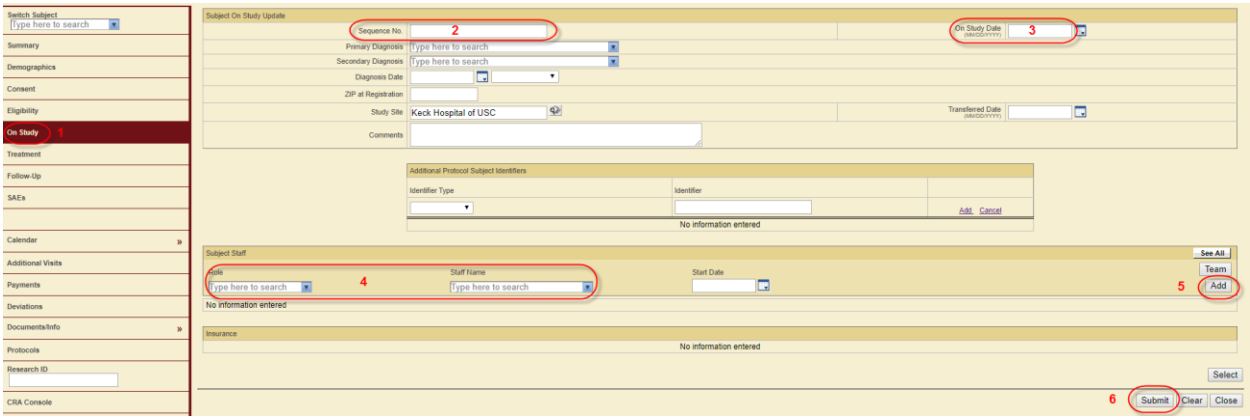
Subject - Status Tracking (Non-Industry Studies)

On Study

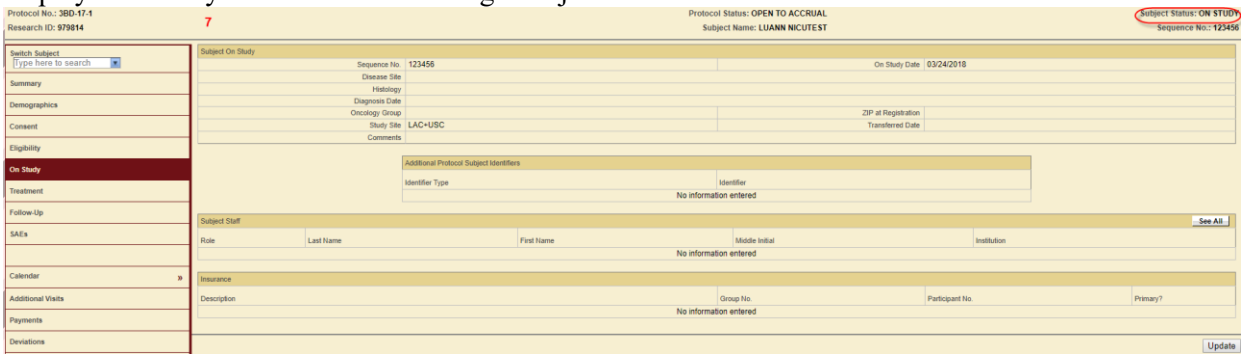
Coordinator has entered an On Study Date

Steps:

1. Click on On Study (left tab)
2. Enter Sequence No (if enabled) – this is the subject protocol no from the sponsor or IVRS
3. Enter On Study Date
4. Add Subject Staff Name and Role (can add more than one)
5. Click Add
6. Click Submit



7. Displays On Study Information and change Subject Status to "ON STUDY"



Subject - Status Tracking (Non-Industry Studies)

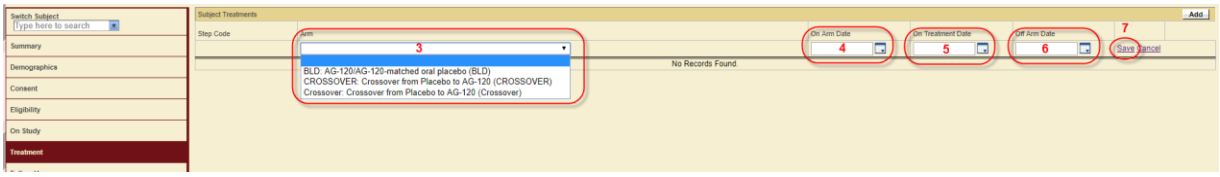
On Treatment

Subject has been enrolled on an Arm, and On Treatment Date has been entered

Steps:

1. Click on On Treatment (left tab) – section to select the appropriate arm of the protocol for which the subject will receive treatment
2. Click on Add

3. Select Arm from the drop down – blinded studies will display one Arm
4. Enter On Arm Date
5. Enter On Treatment Date – activates the Treatment segment of the subject calendar
6. Enter Off Arm Date (if applicable) – where patients start on one Arm and switches to a second Arm at a later point in the study, add Off Arm Date on first Arm before adding the second Arm
7. Click Save



8. Displays Treatment Information and change Subject Status to "ON TREATMENT"

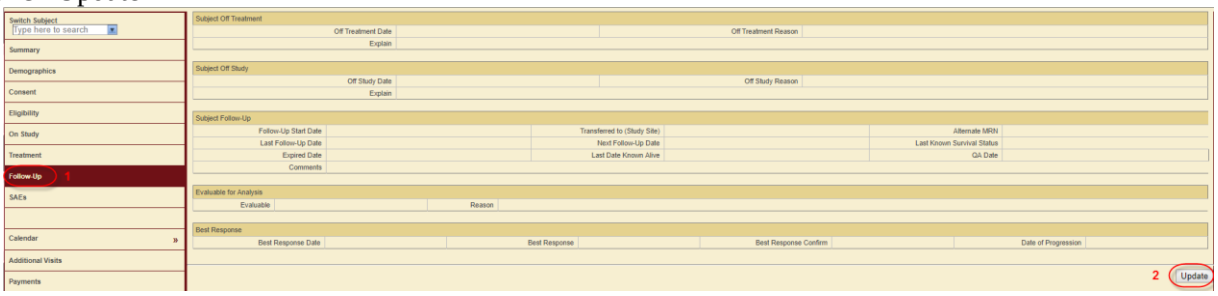
Subject - Status Tracking (Non-Industry Studies)

Off Treatment

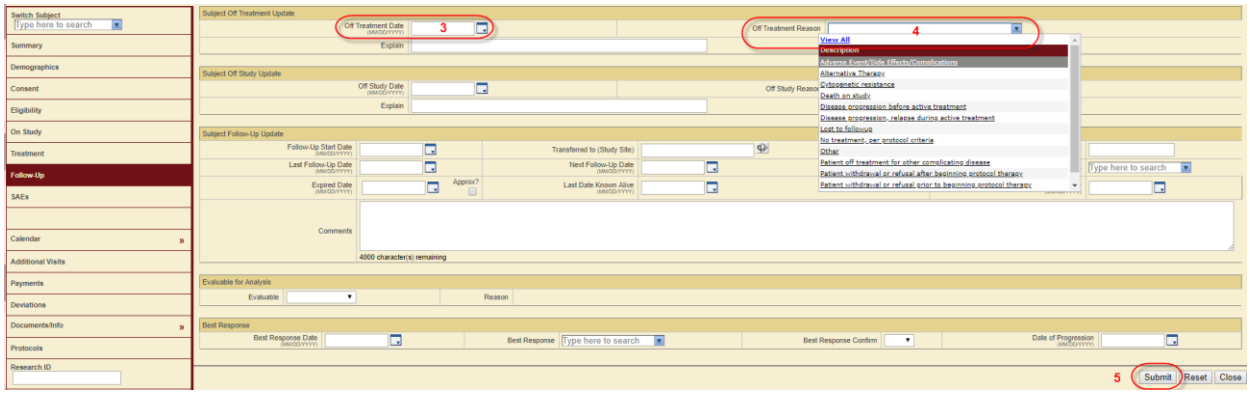
Subject will receive no additional treatment for this study

Steps:

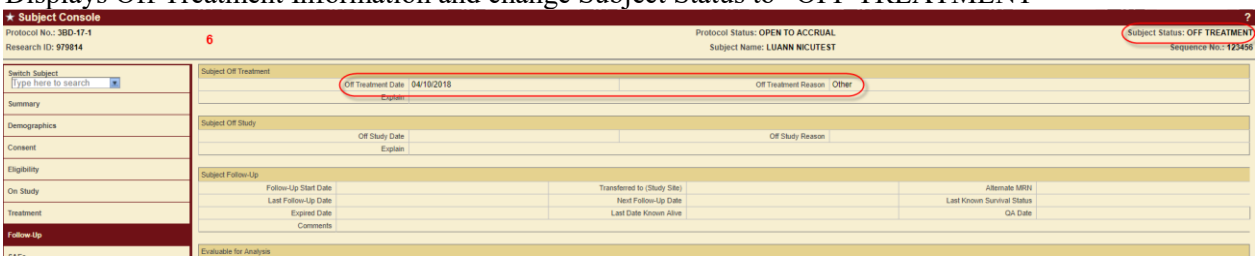
1. Click on Follow-Up (left tab)
2. Click Update



3. Enter Off Treatment Date
4. Select Off Treatment Reason from the drop down
5. Click Submit



6. Displays Off Treatment Information and change Subject Status to "OFF TREATMENT"



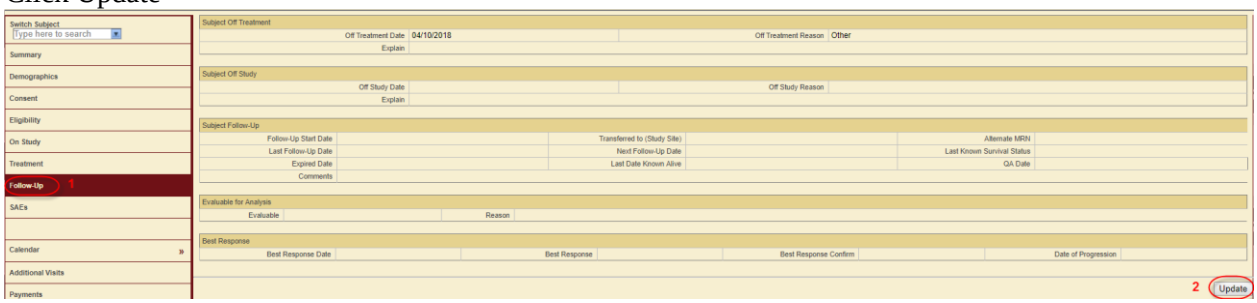
Subject - Status Tracking (Non-Industry Studies)

On Follow Up

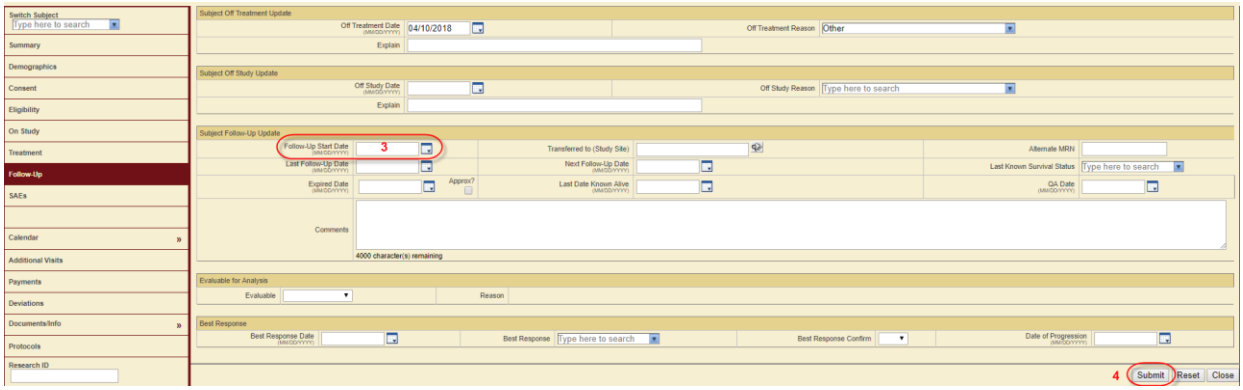
Follow-Up Start Date has been entered (will override Off Treatment)

Steps:

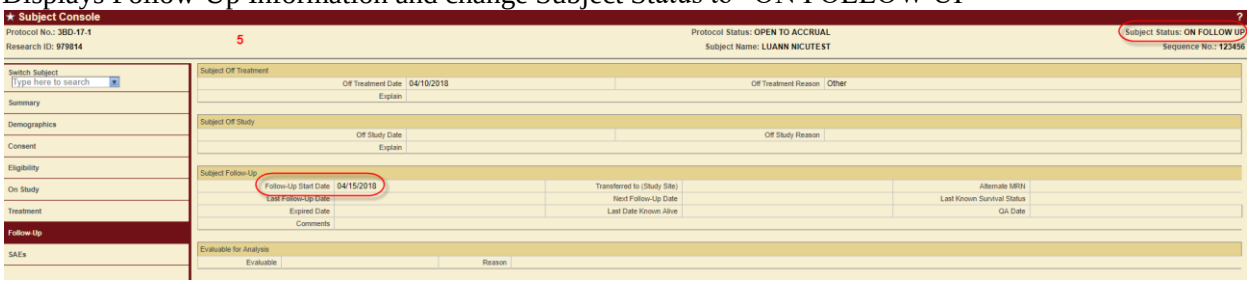
1. Click on Follow-Up (left tab)
2. Click Update



3. Enter Follow-Up Start Date - activates the Follow-Up segment of the subject calendar
4. Click Submit



5. Displays Follow-Up Information and change Subject Status to “ON FOLLOW UP”



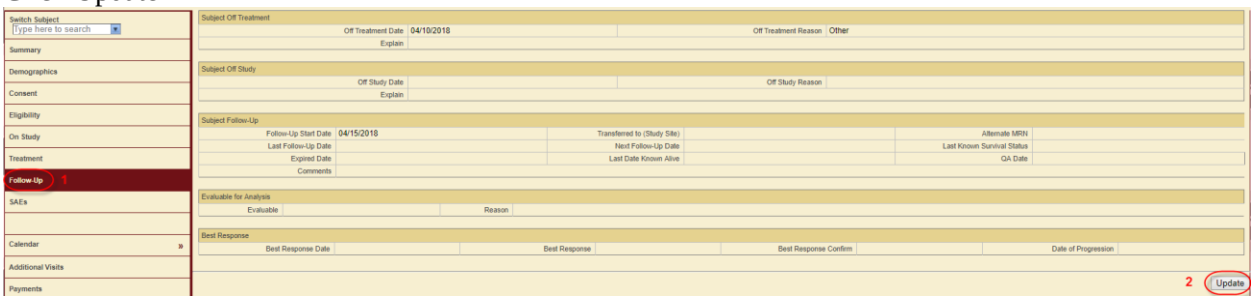
Subject - Status Tracking (Non-Industry Studies)

Off Study

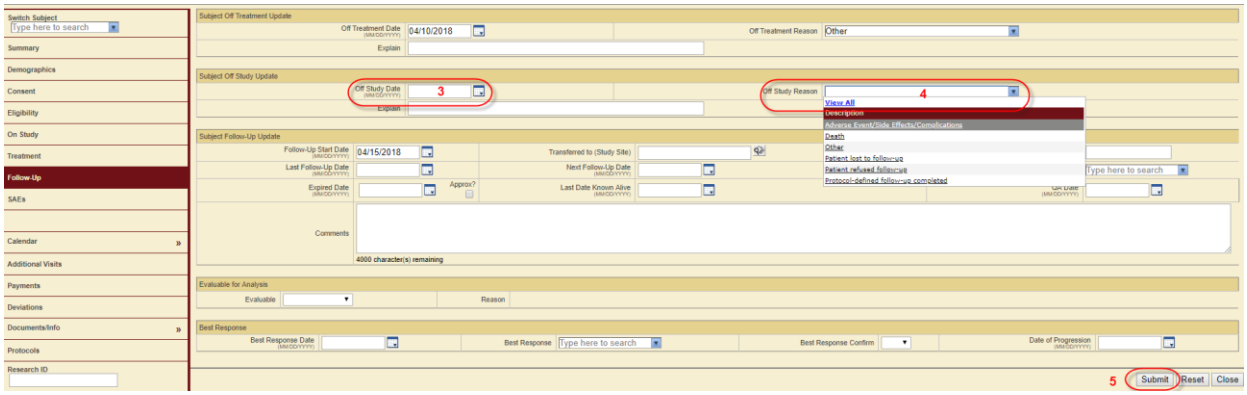
Off Study Date has been entered (will override On Follow Up and Off Treatment)

Steps:

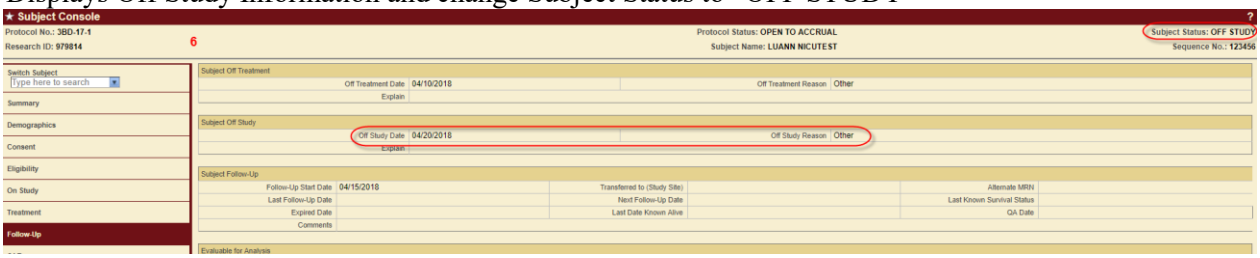
1. Click on Follow-Up (left tab)
2. Click Update



3. Enter Off Study Date
4. Select Off Study Reason from the drop down
5. Click Submit



6. Displays Off Study Information and change Subject Status to “OFF STUDY”



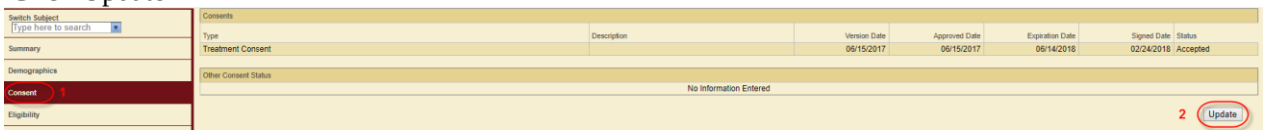
Subject - Status Tracking (Non-Industry Studies)

Withdrawn

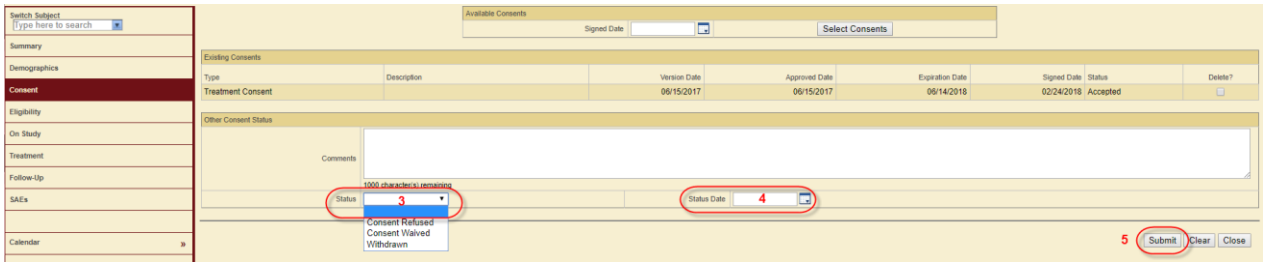
Subject changes mind and no longer consents to treatment

Steps:

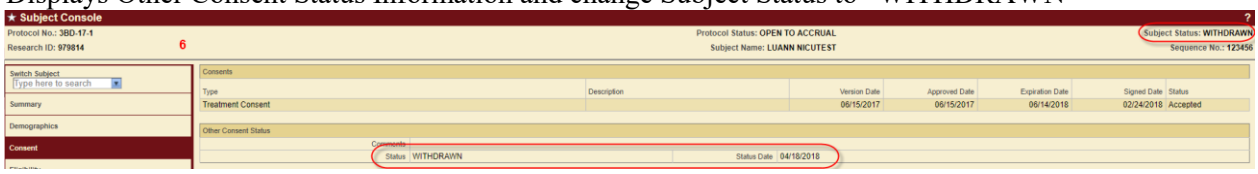
1. Click on Consent (left tab)
2. Click Update



3. Select Status from the drop down (Withdrawn)
4. Enter Status Date
5. Click Submit



6. Displays Other Consent Status Information and change Subject Status to "WITHDRAWN"

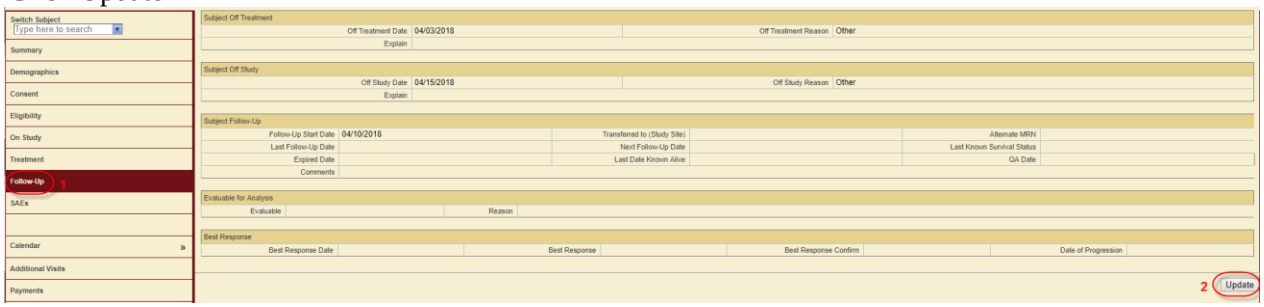


Subject - Status Tracking (Non-Industry Studies)

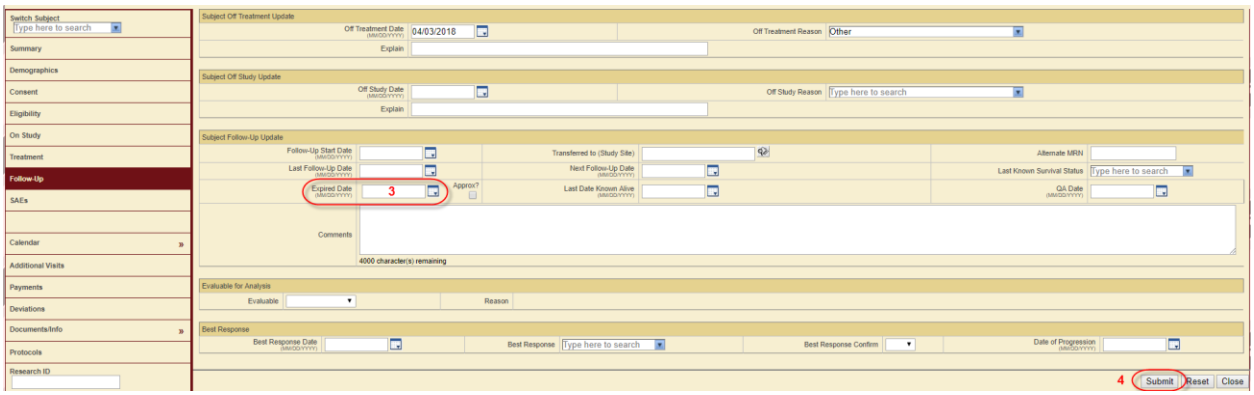
Expired — Subject is no longer alive (may or may not be related to treatment or procedure)

Steps:

1. Click on Follow-Up (left tab)
2. Click Update



3. Enter Expired Date
4. Click Submit



5. Displays Expired Information and change Subject Status to “ (Expired)” – depending at what status the subject expired