Subject - Visit Tracking (Industry Studies)

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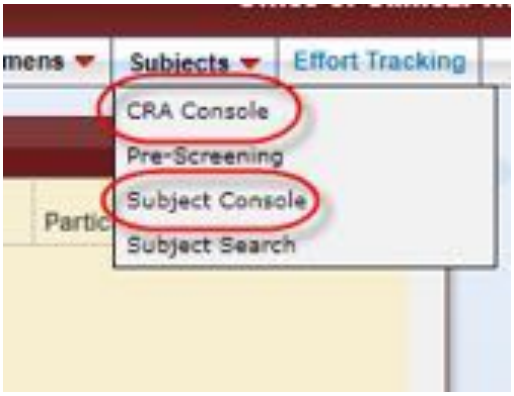
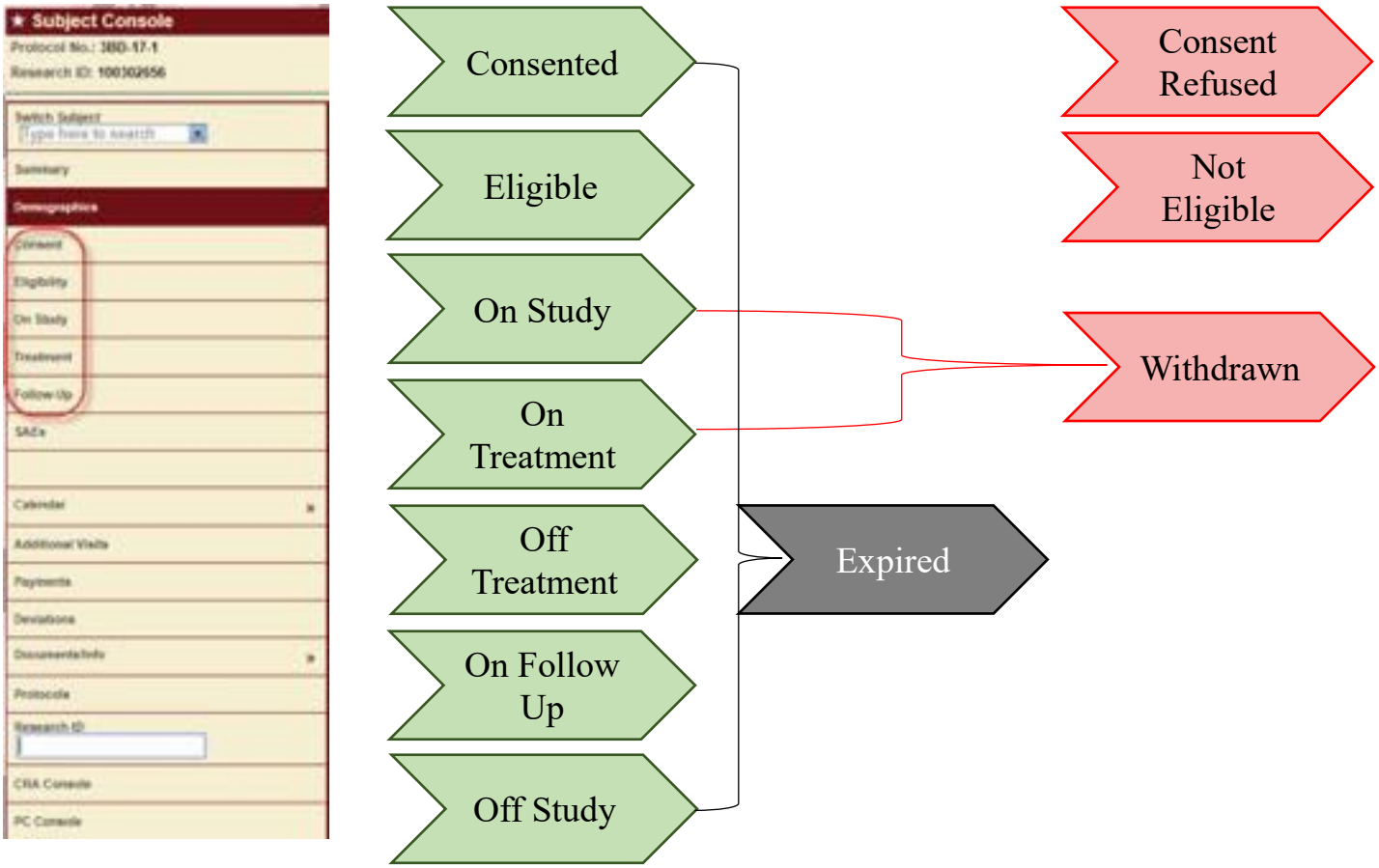
CRA Console – shows all subjects at the protocol level
Subject Console – view individual subject information, such as demographic, consent, eligibility, calendar, etc.



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.



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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"

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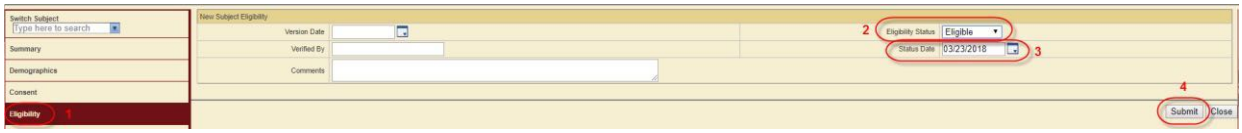
Eligible

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



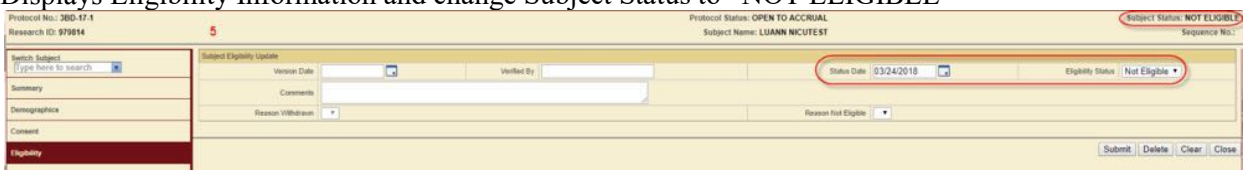
5. Displays Eligibility Information and change Subject Status to "ELIGIBLE"

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"



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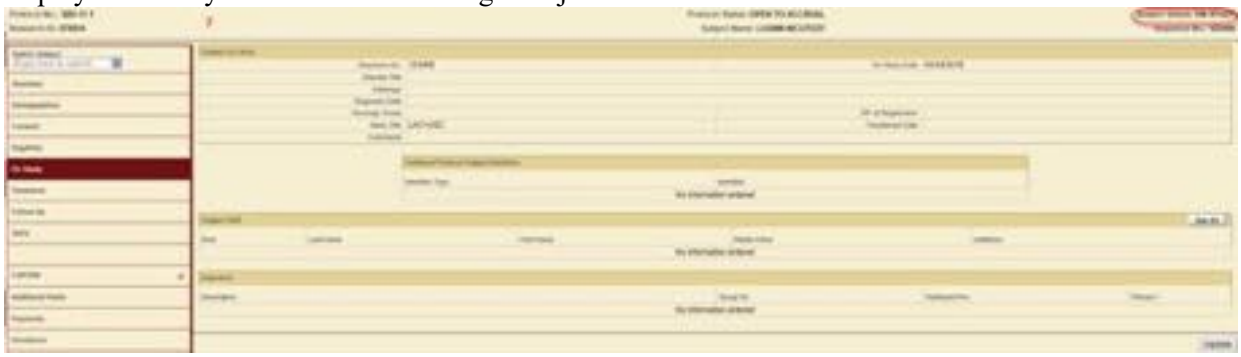
On Study

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"



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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”

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Off Treatment

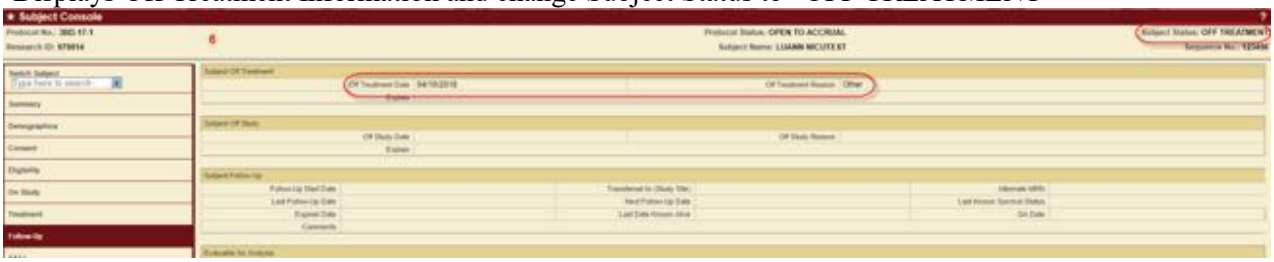
Subject will receive no additional treatment for this study

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"



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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"

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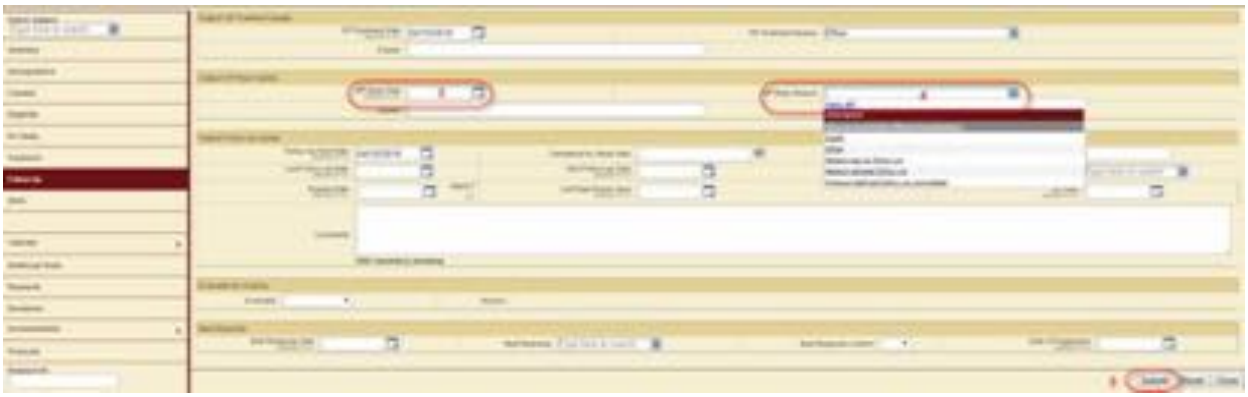
Off Study

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"

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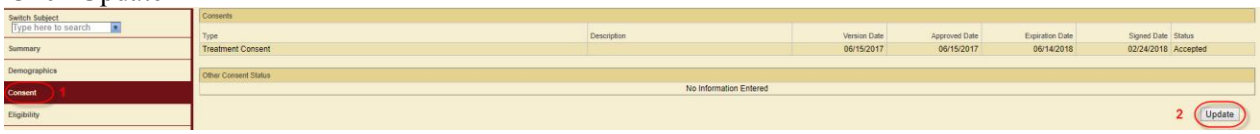
Withdrawn

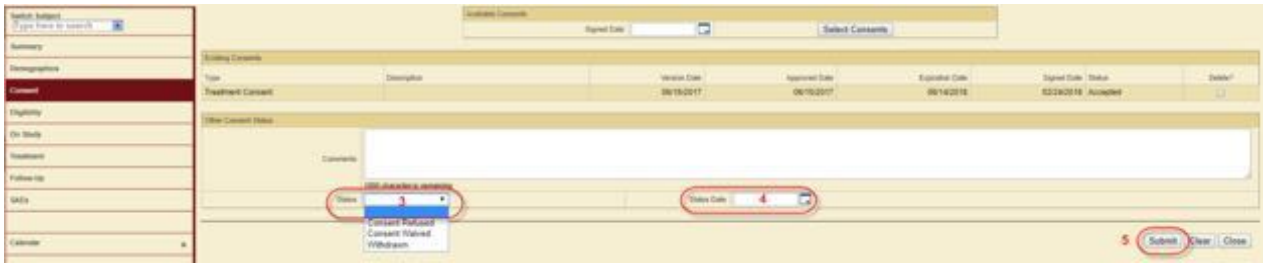
Subject changes mind and no longer consents to treatment

Steps:

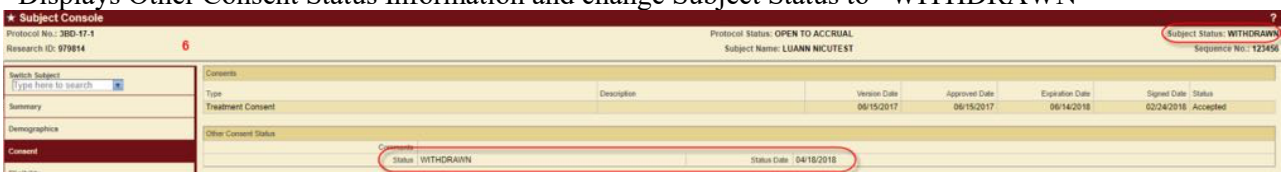
1. Click on Consent (left tab)
2. Click Update



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"



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Expired

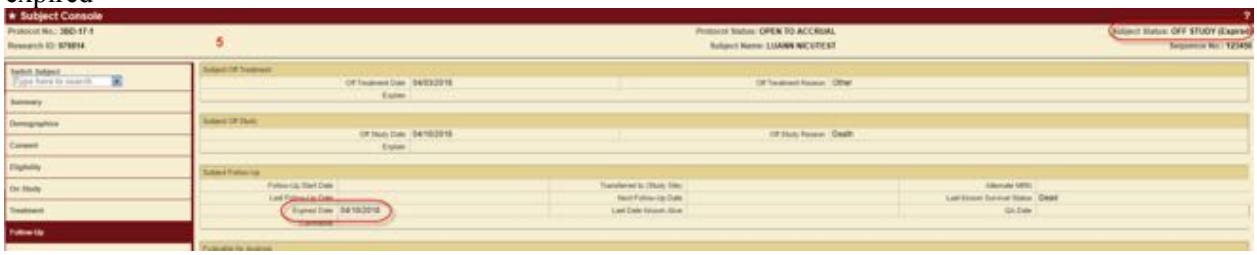
Subject is no longer alive (may or may not be related to treatment or procedure)

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



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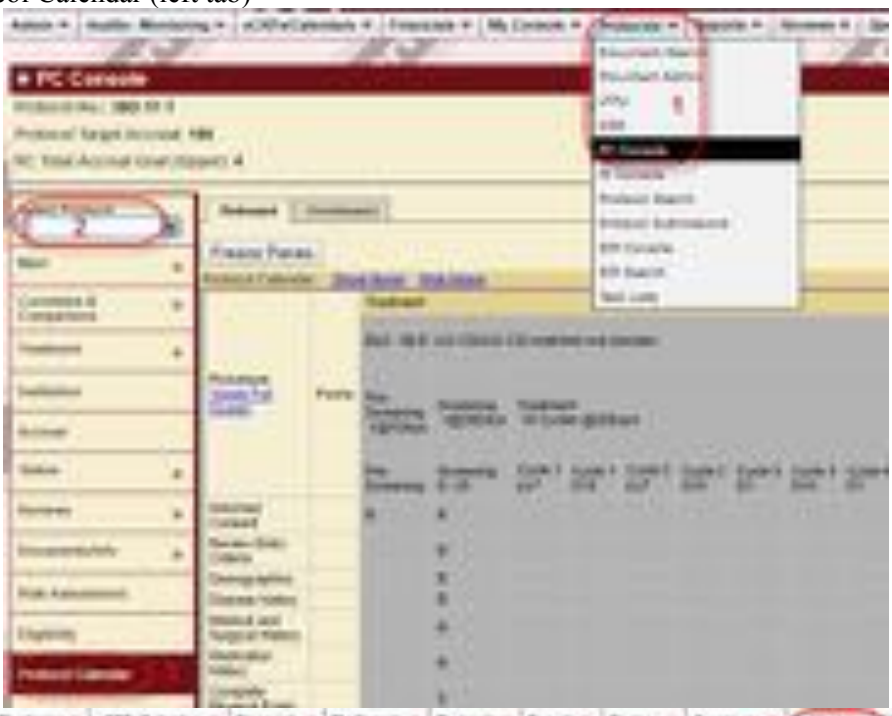
Viewing Protocol Calendar

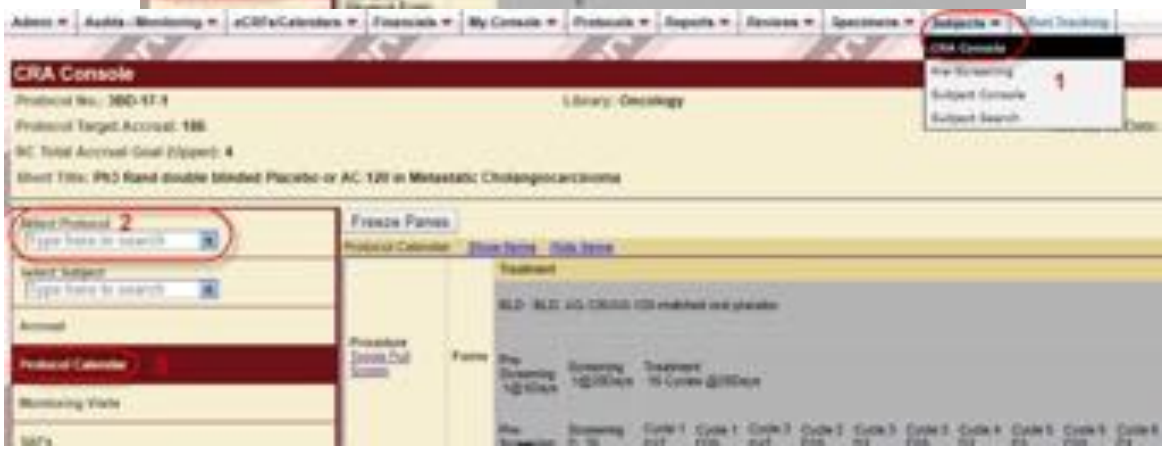
A protocol calendar will display ALL the visit schedule, the expected procedures as well as the billing designations. It is typically built in segments triggered by date entered in the Subject Console:

- Screening/Pre-Treatment – consent signed date
- Treatment – treatment arm, on/off arm date, on/off treatment date
- Off Study – off treatment date, off study date
- Follow-Up – follow-up start date

Steps:

1. Go to Protocol -> PC Console or Subjects -> CRA Console
2. Enter Protocol to search
3. Click on Protocol Calendar (left tab)





Subject - Visit Tracking (Industry Studies)

Viewing Subject Calendar

A subject calendar is specific to the assigned treatment arm and specified visits that pertain to the status of the subject.

Steps:

1. Go to Subjects -> CRA Console
2. Enter Protocol to search
3. Click on the Research ID hyperlink for desired Subject

4. Click Calendar (left tab)
5. Click Calendar (either from the Calendar tab or Calendar subtab)

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Entering Visit Information to Subject Calendar

Steps:

1. Click on the hyperlink for that specific visit

2. Enter the Actual Visit Date
3. Select the Visit Status (Occurred)
4. Enter Procedure Date (optional) – only enter the date for procedures where it is not the same as the actual visit date
5. Missed (optional) – put a check for procedures missed during visit
6. N/A (optional) – put a check for procedures not applicable for that visit

7. Click Submit and Close

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Entering Additional Procedures Done on the Same Visit

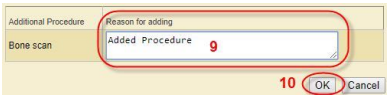
Steps:

1. Click the hyperlink for that specific visit

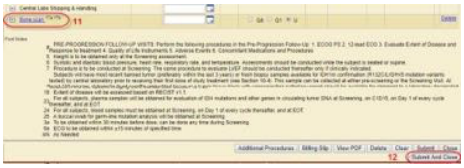
2. Enter the Actual Visit Date
3. Select the Visit Status (Occurred)
4. Enter Procedure Date (optional) – only enter the date for those procedures where it is not the same as the actual visit date
5. Click Submit
6. Click Additional Procedures (it will only show up after clicking Submit)

7. Select Procedure(s) to add
8. Click Submit

9. Enter the Reason for Adding
10. Click OK



11. Procedure added will show at the bottom of the procedure list
12. Click Submit and Close



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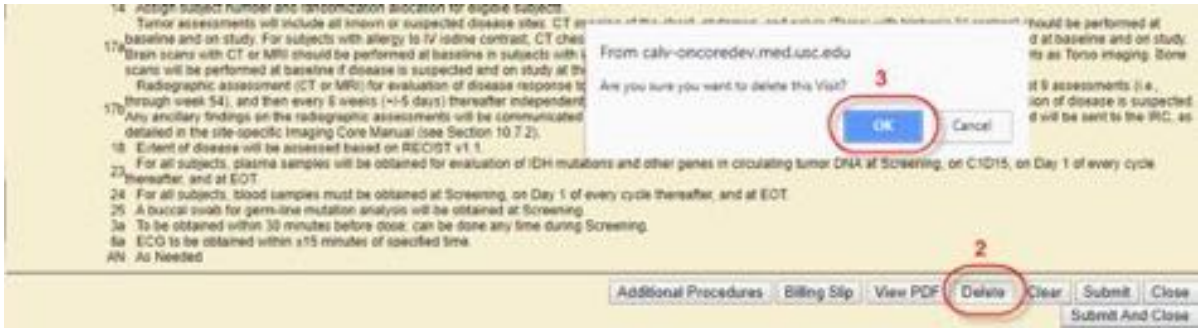
Deleting Visit Entered in Error

Steps:

1. Click on the hyperlink of the visit you want to delete

2. Click Delete (at the bottom of the page)
3. Click OK



4. Visit information is now blank

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Adding Additional Visits

Unscheduled visits that are not on the study calendar as a standard scheduled visit can be added as additional visits. Additional visits will not appear on the subject calendar.

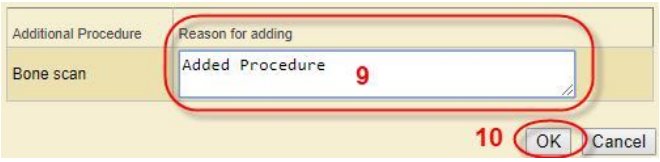
Steps:

1. Click on Additional Visits (left tab)
2. Click New

3. Enter actual Visit Date
4. Enter Visit Description
5. Click Submit
6. Click Additional Procedures (it will only show up after clicking Submit)

7. Select Procedure(s) to add
8. Click Submit

9. Enter the Reason for Adding
10. Click OK



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11. Click Submit and Close

12. Additional Visit added