CISO Study Status Update in OnCore

CISO Regulatory staff will receive “Open To Accrual” notification once CTO completed the signoff. Depending at what stage the study is on, below are the different statuses available.

“Abandoned” status is used for protocols that were created in error/duplicate or we are no longer going to move on with the study. Abandoned is available prior to “Open To Accrual”. “Undo Abandon” will be available when done in error.

Steps:
1. Navigate to Protocols -> PC Console
2. Search for Protocol No
3. Navigate to Status -> Status
4. Click Open
5. Enter Status Date
6. Select Initiator from the drop-down
7. Click Search for Reason
8. Select Reason from the choices
9. Click Submit

10. Click Update

11. Enter Comments
12. Click Submit
13. Click Close

14. Click Undo Abandon (when done in error)
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“Open To Accrual” status indicates that subjects may be registered to the protocol.

Steps:

1. Navigate to Protocols -> PC Console

2. Search for Protocol No
3. Navigate to Status -> Status
4. Click Open

5. Enter Status Date
6. Click Submit
“Suspend” status indicates protocol is temporary closed to accrual and does not allow to place subject On-Study. “Undo Suspend” will be available when done in error. If only a specific Arm is Suspended, please inform oncoresupport@med.usc.edu, do not change the protocol status to Suspend.

Steps:
1. Navigate to Protocols -> PC Console

2. Search for Protocol No
3. Navigate to Status -> Status
4. Click Suspend

5. Enter Status Date
6. Select Initiator from the drop-down
7. Click Search for Reason
8. Select Reason from the choices
9. Click Submit
10. Click Update

11. Enter Comments
12. Click Submit
13. Click Close

14. Click Undo Suspend when done in error
   **DO NOT** click “Undo Suspend” when putting the study back to “Open To Accrual” or “Closed To Accrual”. Clicking undo will not be track as part of status history.
“Closed To Accrual” status indicates protocol does not allow new subject to be registered.

Steps:
1. Navigate to Protocols -> PC Console
2. Search for Protocol No
3. Navigate to Status -> Status
4. Click Close To Accrual
5. Enter Status Date
6. Select Initiator from the drop-down
7. Click Search for Reason
8. Select Reason from the choices
9. Click Submit
“IRB Study Closure” status indicates the final status for the protocol. A warning message will appear if there are still active accrued subject without Off-Study dates. “IRB Study Closure” will be available after “Closed To Accrual”.

Steps:
1. Navigate to Protocols -> PC Console
2. Search for Protocol No
3. Navigate to Status -> Status
4. Click IRB Study Closure
5. Enter Status Date
6. Click Submit
7. Click Close