

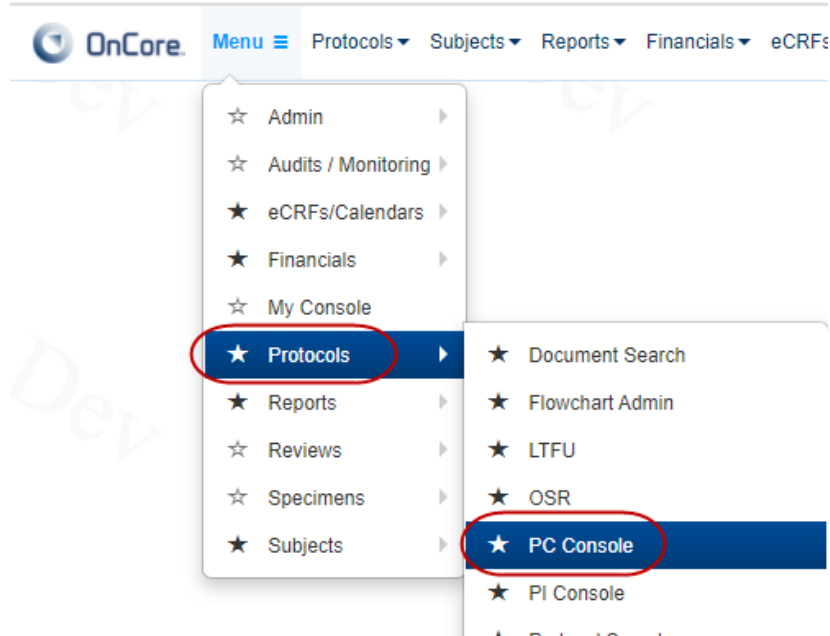
CISO Study Status Update in OnCore

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

The screenshot shows the PC Console interface for protocol LES-TRAIN. The protocol status is 'STUDY TEAM PROTOCOL SIGNOFF'. A table shows the protocol status history with columns for Status Date, Status, Initiator, Change Reason, Comments, and Last Changed By. The 'Status' tab is selected, and the 'Abandon' button is highlighted with a red circle. Other buttons include 'On Hold', 'Open', and 'Undo STUDY TEAM PROTOCOL SIGNOFF'. The 'Update' button is also visible.

Status Date	Status	Initiator	Change Reason	Comments	Last Changed By
06/15/2020	STUDY TEAM PROTOCOL SIGNOFF				Chung, Leslie
06/15/2020	CTO/CCR SIGNOFF				Chung, Leslie
06/01/2020	IRB INITIAL APPROVAL				Chung, Leslie
03/22/2020	NEW				Chung, Leslie

CISO Study Status Update in OnCore

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

Status Date	Status	Initiator	Change Reason	Comments	Last Changed By
07/01/2020	ABANDONED	Department	Other		Chung, Leslie
07/01/2020	STUDY TEAM PROTOCOL SIGNOFF				Chung, Leslie
07/01/2020	PROTOCOL CREATOR SIGNOFF				Chung, Leslie
07/01/2020	IRB INITIAL APPROVAL	Other			Chung, Leslie
03/22/2020	NEW	Other	Other	CTU service order uploaded	Sanchez, Talena

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

Status	Date	Initiator	Reason	Comments
ABANDONED	07/01/2020	Department	Other	Never Opened
STUDY TEAM PROTOCOL SIGNOFF	07/01/2020			
PROTOCOL CREATOR SIGNOFF	07/01/2020			
IRB INITIAL APPROVAL	07/01/2020	Other		
NEW	03/22/2020	Other	Other	CTU service order uploaded

14. Click Undo Abandon (when done in error)

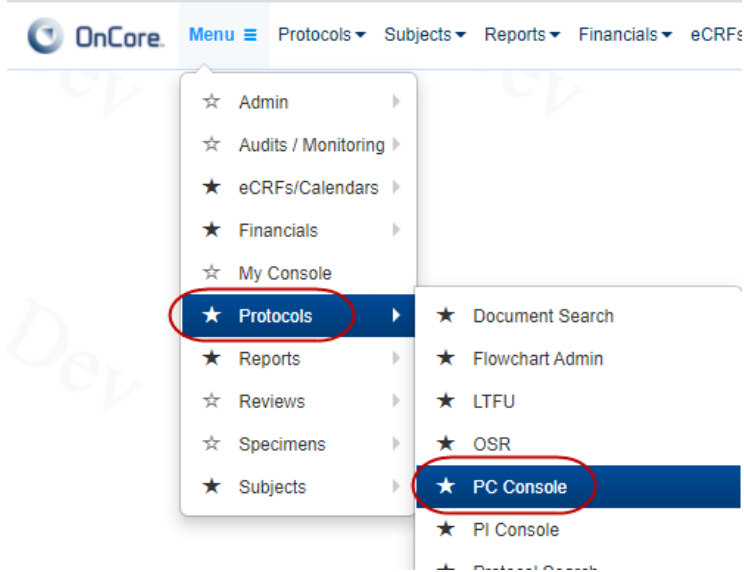
Status Date	Status	Initiator	Change Reason	Comments	Last Changed By
07/01/2020	ABANDONED	Department	Other	Never Opened	Chung, Leslie
07/01/2020	STUDY TEAM PROTOCOL SIGNOFF				Chung, Leslie
07/01/2020	PROTOCOL CREATOR SIGNOFF				Chung, Leslie
07/01/2020	IRB INITIAL APPROVAL	Other			Chung, Leslie
03/22/2020	NEW	Other	Other	CTU service order uploaded	Sanchez, Talena

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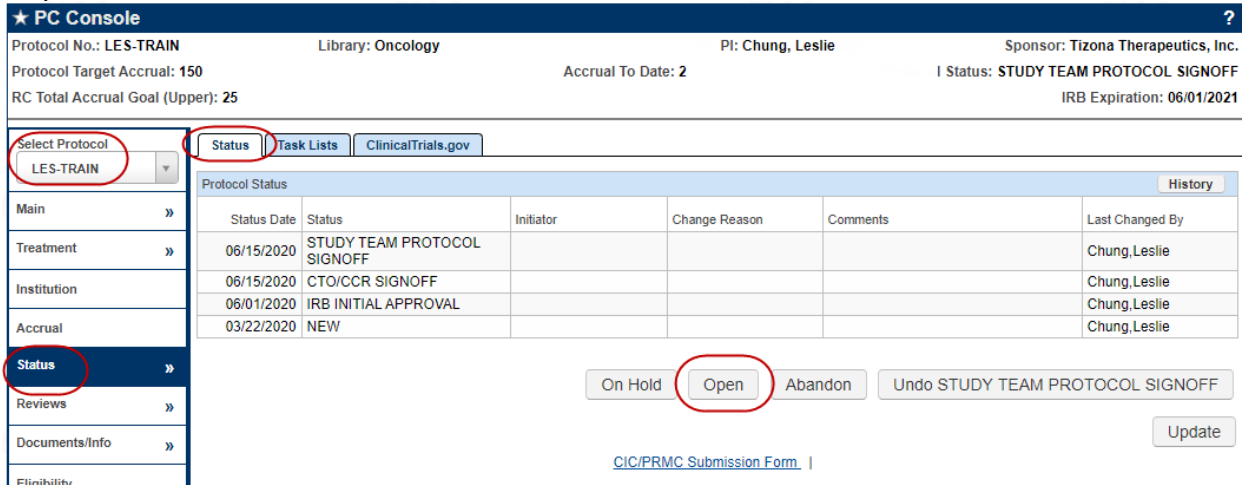
“Open To Accrual” status indicates that subjects may be registered to the protocol.

Steps:

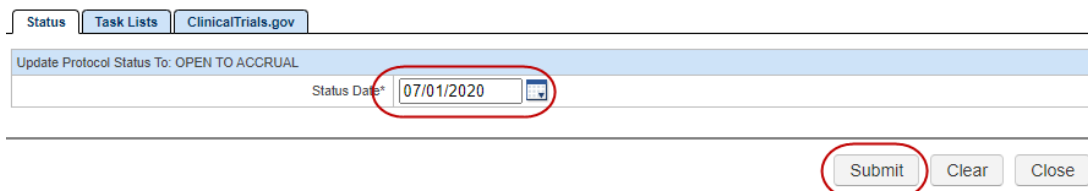
1. Navigate to Protocols -> PC Console



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



5. Enter Status Date
6. Click Submit

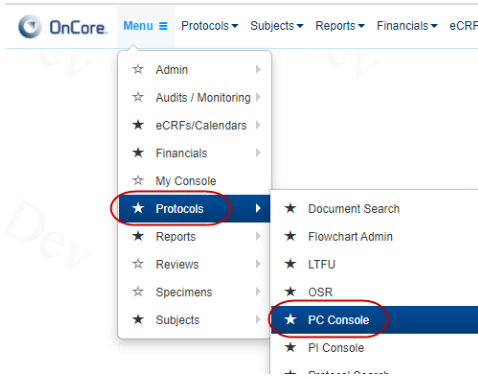


CISO Study Status Update in OnCore

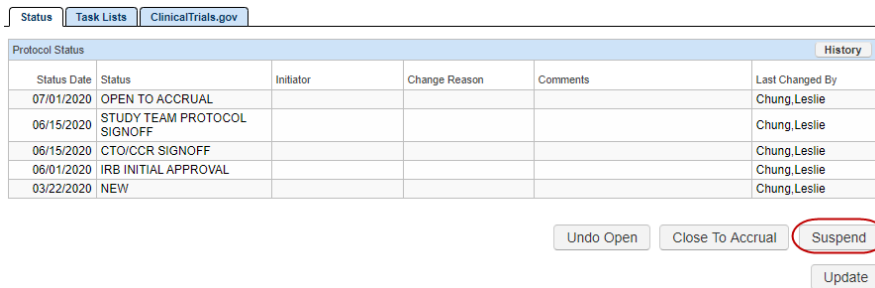
“Suspend” status indicates protocol is temporary closed to accrual and does not allow to place subject On-Study. “Undo Suspend” will be available when done in error. If only a specific Arm is Suspended, please inform oncoresupport@med.usc.edu, do not change the protocol status to Suspend.

Steps:

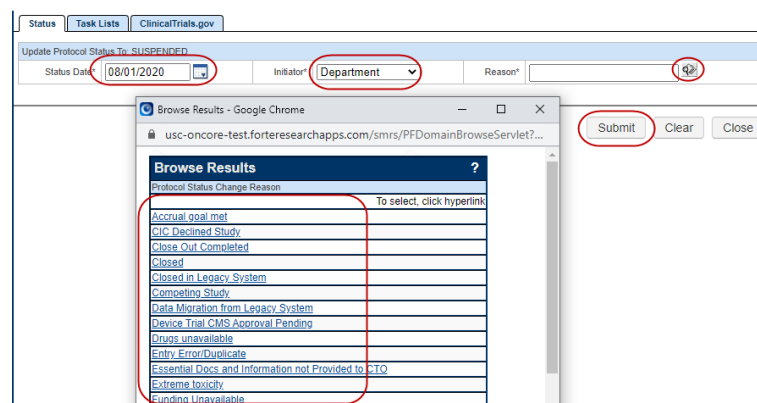
1. Navigate to Protocols -> PC Console



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



CISO Study Status Update in OnCore

10. Click Update

Status Task Lists ClinicalTrials.gov

Protocol Status						History
Status Date	Status	Initiator	Change Reason	Comments	Last Changed By	
08/01/2020	SUSPENDED	Department	Other		Chung, Leslie	
07/01/2020	OPEN TO ACCRUAL				Chung, Leslie	
07/01/2020	STUDY TEAM PROTOCOL SIGNOFF				Chung, Leslie	
07/01/2020	PROTOCOL CREATOR SIGNOFF				Chung, Leslie	
07/01/2020	IRB INITIAL APPROVAL	Other			Chung, Leslie	
03/22/2020	NEW	Other	Other	CTU service order uploaded	Sanchez, Talena	

Undo Suspend Open Close To Accrual **Update**

CIC/PRMC Submission Form |

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

Status Task Lists ClinicalTrials.gov

Protocol Status						History
Status	Date	Initiator	Reason	Comments		
SUSPENDED	08/01/2020	Department	Other	Suspended until pv6 is approved		
OPEN TO ACCRUAL	07/01/2020					
STUDY TEAM PROTOCOL SIGNOFF	07/01/2020					
PROTOCOL CREATOR SIGNOFF	07/01/2020					
IRB INITIAL APPROVAL	07/01/2020	Other				
NEW	03/22/2020	Other	Other	CTU service order uploaded		

Submit Clear 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.

Status Task Lists ClinicalTrials.gov

Protocol Status						History
Status Date	Status	Initiator	Change Reason	Comments	Last Changed By	
08/01/2020	SUSPENDED	Department	Other	Suspended until pv6 is approved	Chung, Leslie	
07/01/2020	OPEN TO ACCRUAL				Chung, Leslie	
07/01/2020	STUDY TEAM PROTOCOL SIGNOFF				Chung, Leslie	
07/01/2020	PROTOCOL CREATOR SIGNOFF				Chung, Leslie	
07/01/2020	IRB INITIAL APPROVAL	Other			Chung, Leslie	
03/22/2020	NEW	Other	Other	CTU service order uploaded	Sanchez, Talena	

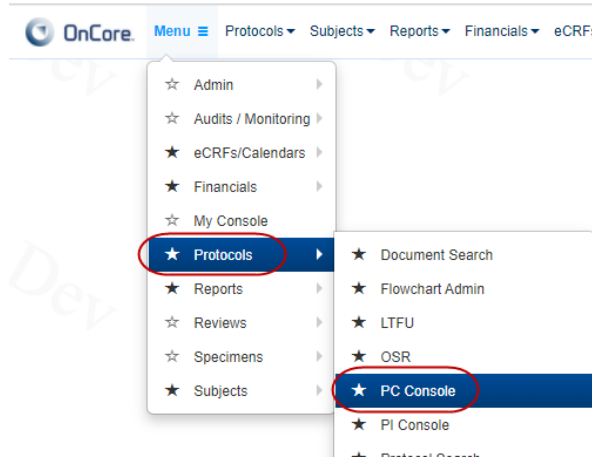
Undo Suspend Open Close To Accrual Update

CISO Study Status Update in OnCore

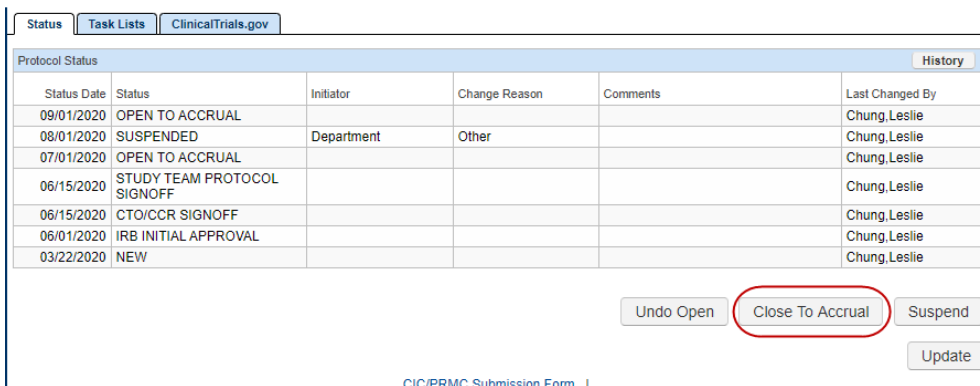
“Closed To Accrual” status indicates protocol does not allow new subject to be registered.

Steps:

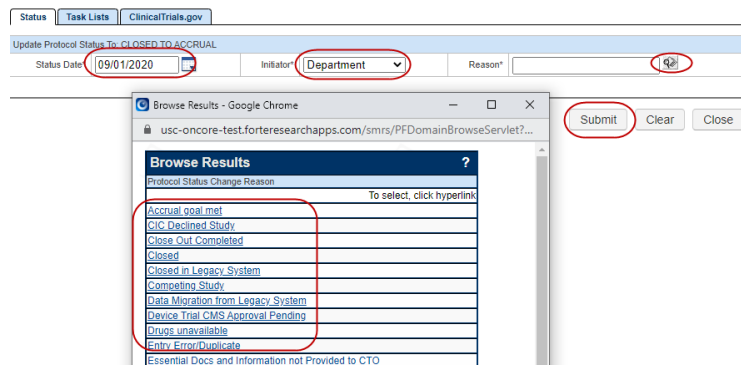
1. Navigate to Protocols -> PC Console



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

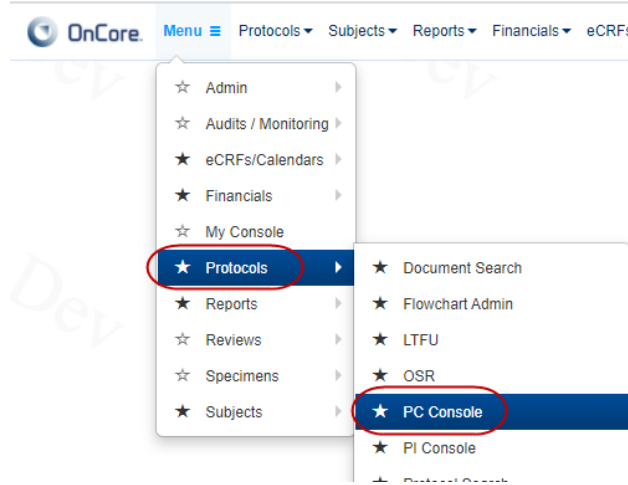


CISO Study Status Update in OnCore

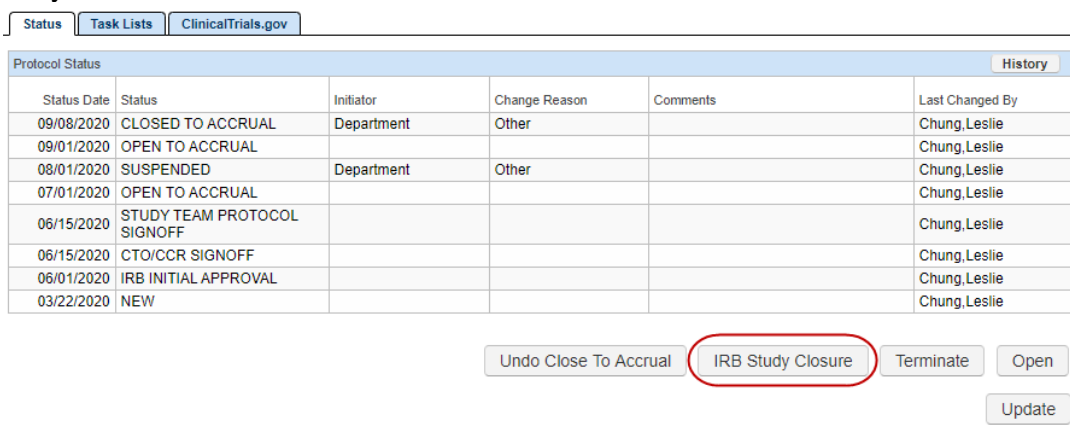
“IRB Study Closure” status indicates the final status for the protocol. A warning message will appear if there are still active accrued subject without Off-Study dates. “IRB Study Closure” will be available after “Closed To Accrual”.

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

