



OnCore – Updating Study Status

Purpose: OnCore is a Clinical Trial Management System (CTMS) from Advarra and gives research teams a single, comprehensive system for managing a trial throughout its life cycle. The University of Arizona Health Sciences (UAHS) uses OnCore for a variety of purposes, including managing all clinical trials conducted within UAHS, housing current and approved study documents, housing study calendars and documenting when patient visits have occurred, housing electronic case report forms (eCRF's) for investigator initiated trials (IIT's), creating and running reports, reporting data directly to the National Cancer Institute (NCI), and tracking staff effort on trials.

OnCore has the functionality to reflect a study's status (open to accrual, closed to accrual, etc.). Reports and websites are linked to OnCore's study status, so it is important to keep this up-to-date. The purpose of this work practice is to describe the process for updating a study's status in OnCore.

Scope: This applies to regulatory staff.

Tools

- Learning Portal: <https://oncore-docs.advarra.com/index.php>
In addition, you can log into OnCore and from your profile drop down, select Help → Learning Portal

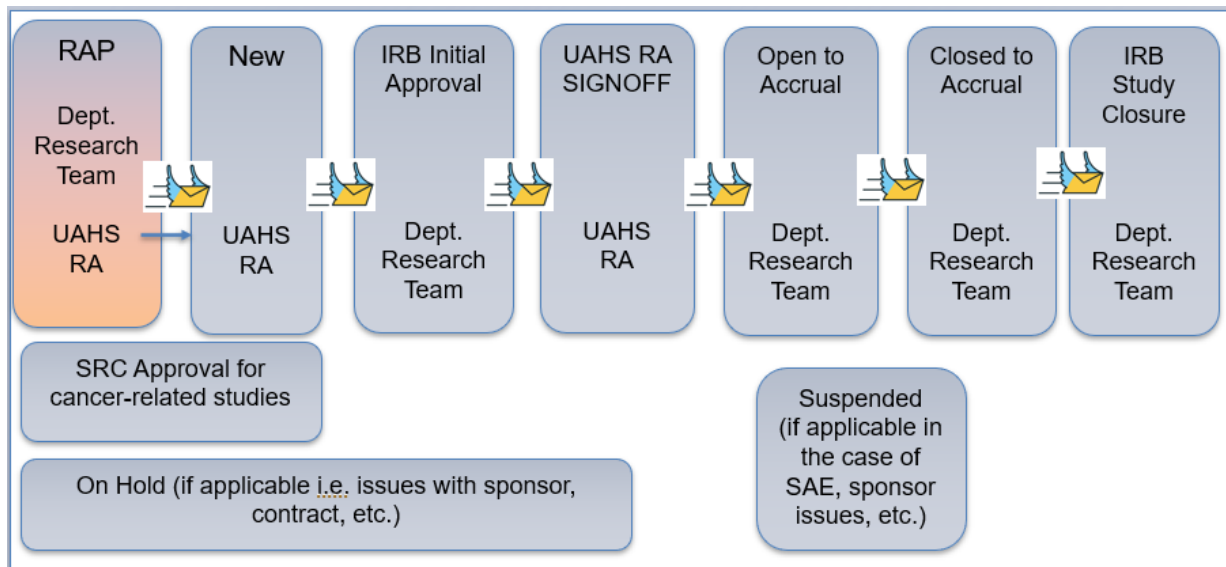
Process / Steps:

1. Log into OnCore: <https://login.advarracloud.com/>
2. Go to "Protocols" → "PC Console," and search for the appropriate protocol.
3. Click on the "Status" tab.



Regulatory Work Practice

4. Usual Status Flow:



5. The following status updates are generated, and do not need to be manually entered by regulatory staff:

- Studies that have just been entered into OnCore (either via Cancer Center Scientific Review Committee [SRC] submission or Research Administration Portal [RAP] submission) will populate with a date and a status of “New.”
- Studies that have received SRC approval will populate with a date and a status of “SRC Approval” for cancer related studies.
- When initial IRB approval has been received from the IRB of record and entered correctly into OnCore, the study record will populate with a date and a status of “IRB Initial Approval”. See the Updating IRB Reviews guidance for more information.

StatusTask ListsClinicalTrials.gov

Protocol StatusHistory

Status Date	Status	Initiator	Change Reason	Comments	Last Changed By
03/27/2017	IRB INITIAL APPROVAL				Suckra, Kerry-Ann
02/06/2020	NEW				Suckra, Kerry-Ann

On Hold

Abandon

Update

- Before opening to accrual, the study needs to have UAHS RA Signoff. This is completed by UAHS Research Administration following completion of all required items, including CARM signature, CTA completion, and receipt of final ICFs.



Regulatory Work Practice

6. If a study is rejected at any point prior to receiving initial IRB approval, abandon the study in OnCore.
 - a. Click “Abandon.”
 - b. Enter the status date as the date the study was rejected.
 - c. Enter the initiator, as appropriate. (Ex. If the PI chose to reject the trial, select “PI.” If the sponsor chose to stop the study or reject UAHS, select “Pharmaceutical Company.”)
 - d. Select from the options for the reason for status change. Note, if any of the options do not apply, select “Other (specify).” After selecting an option, you will be directed to the main status screen.

Status | Task Lists | ClinicalTrials.gov

Protocol Status History

Status Date	Status	Initiator	Change Reason	Comments	Last Changed By
03/27/2017	IRB INITIAL APPROVAL				Suckra, Kerry-Ann
02/06/2020	NEW				Suckra, Kerry-Ann

On Hold CARM Approval Signoff **1** Abandon Update

Update Protocol Status To: ABANDONED

2 Status Date*  Initiator*  **3** Reason*  **4**

Cancer Center

FDA

Federal FUnders

IRB

NIH

Other

Pharmaceutical Company

PI

SYSTEM

VA

6 Submit Clear Close

Browse Results ?

Protocol Status Change Reason

To select, click hyperlink

[Accrual goal met](#)

[Drugs unavailable](#)

[Extreme toxicity](#)

[Insufficient staff](#)

[Competing studies](#)

[Slow accrual](#)

[Other \(specify\)](#) **5** Close

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Regulatory Work Practice

- e. To add comments, click “Update,” and add any applicable comments. Press “Submit” and “Close” to return to the main screen. Note: always add comments when selecting “Other.”

The screenshot shows the 'Protocol Status' form with tabs for Status, Task Lists, and ClinicalTrials.gov. The 'Status' tab is active, displaying a table of protocol status changes. Below the table, there is a form to update the status. The 'Status' dropdown is set to 'ABANDONED', the 'Date' is '03/21/2020', and the 'Initiator' is 'PI'. The 'Reason' dropdown is set to 'Other (specify)'. The 'Comments' field is empty. The 'Update' button is highlighted with a red circle 1. The 'Submit' button is highlighted with a red circle 3. The 'Close' button is highlighted with a red circle 4.

Status Date	Status	Initiator	Change Reason	Comments	Last Changed By
03/21/2020	ABANDONED	PI	Other (specify)		Johnson,Me Linda
03/27/2017	IRB INITIAL APPROVAL				Johnson,Me Linda
02/06/2020	NEW				Suckra,Kerry-Ann

On Hold Undo Abandon

Status Date Initiator Reason Comments

ABANDONED 03/21/2020 PI Other (specify) Reason for abandoning

Submit Clear Close

7. The study team is responsible for updating the study status to Open to Accrual when the study opens to enrollment.
- a. Click on “Open to Accrual.” The date should be the date the study opens to accrual. This is often the date of the sponsor’s/CRO’s activation letter.

The screenshot shows the 'Protocol Status' form with tabs for Status, Task Lists, and ClinicalTrials.gov. The 'Status' tab is active, displaying a table of protocol status changes. Below the table, there is a form to update the status. The 'Status' dropdown is set to 'Open'. The 'Date' is empty. The 'Initiator' is empty. The 'Reason' dropdown is set to 'Other (specify)'. The 'Comments' field is empty. The 'Update' button is highlighted with a red circle 1. The 'Submit' button is highlighted with a red circle 3. The 'Close' button is highlighted with a red circle 4.

Status Date	Status	Initiator	Change Reason	Comments	Last Changed By
04/01/2017	FE CONTRACT SIGNOFF				Johnson,Me Linda
04/01/2017	CARM APPROVAL SIGNOFF				Johnson,Me Linda
03/27/2017	IRB INITIAL APPROVAL				Johnson,Me Linda
02/06/2020	NEW				Suckra,Kerry-Ann

On Hold Open Abandon Undo FE CONTRACT SIGNOFF

Update

Update Protocol Status To: OPEN TO ACCRUAL

Status Date

Submit Clear Close

8. If a study is temporarily closed to accrual but plans to re-open, or if the study is otherwise suspended, update the study status.
- a. Click on “Suspend.”



Regulatory Work Practice

- b. Enter the date the study was suspended, the initiator, and the reason. Note, if any of the options do not apply, select “Other (specify).” Always add comments when selecting “Other.”

Protocol Status						History
Status Date	Status	Initiator	Change Reason	Comments	Last Changed By	
04/15/2017	OPEN TO ACCRUAL				Johnson, Me Linda	
04/01/2017	FE CONTRACT SIGNOFF				Johnson, Me Linda	
04/01/2017	CARM APPROVAL SIGNOFF				Johnson, Me Linda	
03/27/2017	IRB INITIAL APPROVAL				Johnson, Me Linda	
02/06/2020	NEW				Suckra, Kerry-Ann	

Undo Open Close To Accrual **Suspend** Update

Update Protocol Status To: SUSPENDED

2 Status Date* **3** Initiator* **4** Reason*

- Cancer Center
- FDA
- Federal FUnders
- IRB
- NIH
- Other
- Pharmaceutical Company
- PI
- SYSTEM
- VA

6 Submit **7** Clear **Close**

5 Browse Results

Protocol Status Change Reason

- Accrual goal met
- Drugs unavailable
- Extreme toxicity
- Insufficient staff
- Competing studies
- Slow accrual
- Other (specify)

Protocol Status				
Status Date	Status	Initiator	Change Reason	Comments
06/01/2017	SUSPENDED	PI	Other (specify)	Temporarily suspended because reached enrollment target for Early Safety Assessment cohort.



Regulatory Work Practice

- c. After the study re-opens to accrual, click “Open,” and enter the applicable information.
Do **not** click “Undo Suspend.”

Protocol Status						History
Status Date	Status	Initiator	Change Reason	Comments	Last Changed By	
06/01/2017	SUSPENDED	PI	Other (specify)	Temporarily suspended because reached enrollment target for Early Safety Assessment cohort.	Johnson,Me Linda	
04/15/2017	OPEN TO ACCRUAL				Johnson,Me Linda	
04/01/2017	FE CONTRACT SIGNOFF				Johnson,Me Linda	
04/01/2017	CARM APPROVAL SIGNOFF				Johnson,Me Linda	
03/27/2017	IRB INITIAL APPROVAL				Johnson,Me Linda	
02/06/2020	NEW				Suckra,Kerry-Ann	

Undo Suspend

Open

Close To Accrual

Update

Update Protocol Status To: OPEN TO ACCRUAL

Status Date*

Submit

Clear

Close

Protocol Status						History
Status Date	Status	Initiator	Change Reason	Comments	Last Changed By	
07/01/2017	OPEN TO ACCRUAL				Johnson,Me Linda	
06/01/2017	SUSPENDED	PI	Other (specify)	Temporarily suspended because reached enrollment target for Early Safety Assessment cohort.	Johnson,Me Linda	
04/15/2017	OPEN TO ACCRUAL				Johnson,Me Linda	

9. Update the study status when the study closes to accrual.
- Click on “Close to Accrual.”
 - Enter the date the study was closed to accrual, the initiator, and the reason. Note, if any of the options do not apply, select “Other (specify).” Always add comments when selecting “Other.”

Protocol Status			
Status Date	Status	Initiator	Change Reason
12/31/2019	CLOSED TO ACCRUAL	Pharmaceutical Company	Accrual goal met



Regulatory Work Practice

10. Update the study status when the study is concluded with the IRB.

- a. If the closure is a routine closure initiated by the study team or sponsor, click on “IRB Study Closure.” Enter the date of IRB study closure. This is the date of IRB closure approval.

Protocol Status			
Status Date	Status	Initiator	Change Reason
01/31/2020	IRB STUDY CLOSURE		

- b. If the closure is initiated by the IRB due to issues with the study, click on “Terminate.” Enter the date of termination as determined by the IRB.

11. After the study has received initial approval from the IRB of record, it must go through all subsequent statuses in OnCore (UAHS RA Signoff, Open to Accrual, Closed to Accrual, IRB Study Closure/Terminated) in order to be closed. Please reach out to regulatory@arizona.edu and OnCoreSupport@arizona.edu for assistance if the study has been closed without ever opening to accrual.

12. If you enter the status incorrectly and you need to delete it, simply click on the Undo button for that status. You may have to Undo several times to delete the status you wanted deleted. You may want to do a screen shots to save the dates.

