

Description: Before an OnCore protocol can be [opened to accrual](#), all applicable signoffs must be completed. The following signoffs have been implemented at UF:

- Study Team Signoff
- OCR Signoff

STUDY TEAM SIGNOFF (ONCOLOGY LIBRARY ONLY)

- The Study Team Signoff is required before for any new oncology protocol can be opened to accrual.
- Study Team Signoff permission is a standalone Management Group–based permission inside a role called MG-SO-STUDYTEAM. This permission is not automatically bundled with any other role, so this individual role needs to be added to the specific users that need the permission. To request this role, please submit [an OnCore Access Request form](#).
- Verification may include conduction of a Study Initiation Visit (SIV), Sponsor activation approval notification, BEACON build and/or OnCore Calendar build is complete, study drug on site, OCR/EPIC review is complete.
- The UF Health Cancer Center’s clinical research office (CRO) is using the Study Team Signoff as a manager level signoff, but other groups with oncology studies can use this **required** signoff as they see fit.

OCR SIGNOFF (ALL NEW STUDIES)

- The OCR Signoff is required before any new OnCore protocol can be opened to accrual by the Study Team.
- OCR will perform this signoff after all of the following have occurred (**as applicable to the study in question**):
 - IRB initial approval has been recorded in OnCore by the study team.
 - OnCore Calendar has been built and released by OCR Calendar team.
 - Research Billing Compliance review has been completed by the OCR CAB team.
 - OnCore Budget has been entered and released by the OCR CAB team.
 - OnCore Billing Grid has been sent to Epic.
 - Study Contract/Agreement has been executed by the OCR Contracting team.

STEPS TO COMPLETE A SIGNOFF

1. Navigate to **Menu > Protocols > PC Console**.
2. Select your protocol.
3. Navigate to the **Status** vertical tab – available signoff buttons will be displayed on the lower right of the screen.

Note: Signoff buttons are available only in **view-only mode**. If you do not see the buttons, be sure to click the **[Close]** button to exit **update mode**.

Status Date	Status	Initiator	Change Reason	Comments	Last Changed By
05/05/2021	STUDY TEAM SIGNOFF				Trainor, Allison
05/05/2021	IRB INITIAL APPROVAL				Harris, Kyle
04/22/2021	PRMC APPROVAL				Walsh, Judy
04/08/2021	NEW				Trainor, Allison