UPDATE A PROTOCOL STATUS
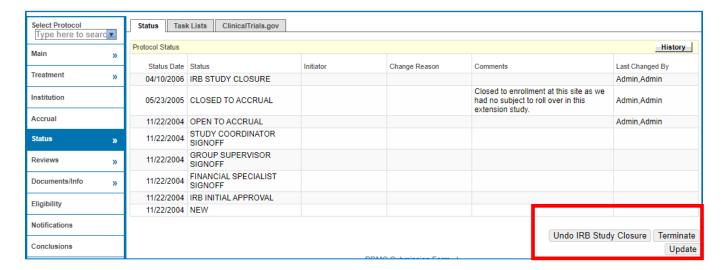
Description: OnCore protocol statuses are assigned (and unassigned) in a predetermined order. Users with the appropriate privileges will see buttons that can be used to assign the next status, undo the current status, or update the order of the protocol's approval statuses.

STEPS TO UPDATE A PROTOCOL STATUS

1. Navigate to **Menu > Protocols > PC Console.**

2. Select your protocol.

3. Navigate to the **Status** vertical tab – available status buttons will be displayed on the lower right of the screen.

4. Click the button that corresponds to the status you are implementing (see each status detail in sections below).

   - New
   - On Hold
   - PRMC Approval
   - IRB Initial Approval
   - Study Team Signoff
   - OCR Signoff
   - Open to Accrual
   - Suspended
   - Closed to Accrual
   - IRB Study Closure
   - Abandoned
   - Terminated

5. Enter the following:

   - **Status Date**
   - **Initiator**
   - **Reason**

6. Click **[Submit]**

NEW

Status Group: Pending

Trigger: The protocol has been created in OnCore

Responsibility: The Office of Clinical Research (OCR) or Scientific Review and Monitoring Committee (cancer studies)

Description: OnCore protocols have a status of **NEW** until the first required review is documented for the study.

ON HOLD

Status Group: Pending

Trigger: [On Hold] button at PC Console > Status

Responsibility: Study Team

Description:

- A study may be placed **On Hold** if there is an unplanned delay in the activation process.

- This delay could be due to issues on the sponsor's side (e.g. supply issues for investigational product) or on the investigator's side (e.g. lack of resources to open the study).

- The **On Hold** button is displayed until the protocol status becomes **Open to Accrual**.

- The **Off Hold** button is displayed when a protocol is **On Hold**.

- When a protocol is removed from **On Hold** status by clicking **Off Hold**, the protocol reverts to its previous status. In this way, the **Off Hold** status undoes the **On Hold** status (and vice versa), so other functionality to undo the status change is not available for these statuses.

- When an approved Initial IRB Review or an approved Initial PRMC Review is entered for a protocol having the status **On Hold**, OnCore updates the status of the protocol to **IRB Initial Approval** or **PRMC Approval** and inserts an **Off Hold** status into the table.

PRMC APPROVAL

Status Group: Pending

Trigger: PRMC Approval has been documented in OnCore

Responsibility: UF Health Cancer Center Scientific Review and Monitoring Committee (SRMC)

Description:

- The protocol has been reviewed and/or approved by the SRMC (also known as the Protocol Review and Monitoring Committee - PRMC) and documented in OnCore.

- The PRMC/SRMC reviews the scientific merit, methodology and validity of statistical analyses of cancer-relevant studies prior to activation.

- The committee will ensure proper prioritization of studies and the ability to monitor all cancer-related studies for expected progress relating to accrual goals and performance standards.

- When PRMC Approval is documented by the PRMC/SRMC, the protocol status is automatically updated.

IRB INITIAL APPROVAL

Status Group: Pending

Trigger: IRB Approval has been documented in OnCore

Responsibility: Study Team

Description:

- This status is automatically updated when an IRB Initial Approval has been documented by the study team.

- For more information, see the OnCore user guide [Document an IRB Review](#).

STUDY TEAM SIGNOFF (ONCOLOGY LIBRARY ONLY)

Status Group: Pending

Trigger: [Study Team Signoff] button at PC Console > Status

Responsibility: Cancer Study Team

Description:

- See the [Complete Signoffs](#) user guide.

OCR SIGNOFF

Status Group: Pending

Trigger: [OCR Signoff] button at PC Console > Status

Responsibility: The Office of Clinical Research (OCR)

Description:

- See the [Complete Signoffs](#) user guide.

OPEN TO ACCRUAL

Status Group: Active

Trigger: [Open] button at PC Console > Status

Responsibility: Study Team

Description:

- Once the [IRB Initial Approval has been documented](#) and all other signoffs have been completed, a protocol status can be changed to **Open to Accrual** in OnCore by the study team.

- For more information, see the OnCore user guide [Open an OnCore Protocol to Accrual](#).

SUSPENDED

Status Group: Active

Trigger: [Suspend] button at PC Console > Status

Responsibility: Study Team

Description:

- This status indicates that a protocol is temporarily closed to accrual; Protocols often re-open after suspension.
- OnCore does not allow you to place subjects **On Study** when a protocol is **suspended**.
- The protocol should not be reopened to accrual until issues are resolved (e.g. site initiation visit).
- The **Suspend** button is displayed once a protocol has been **Open to Accrual.**
- The **Undo Suspend** button is displayed once a protocol has been **Suspended.**
- When a protocol is removed from **Suspend** status by clicking **Undo Suspend**, the protocol reverts to its previous status.

CLOSED TO ACCRUAL

Status Group: Active

Trigger: [Close to Accrual] button at PC Console > Status

Responsibility: Study Team

Description:

- Subjects may be active in treatment or follow-up, however no additional subjects may be placed on study.
- Accrual target has been reached.
- Subjects can no longer be added to the study.
- Results can still be collected and recorded.
- Data is being analyzed.

IRB STUDY CLOSURE

Status Group: Completed

Trigger: [IRB Study Closure] button at PC Console > Status

Responsibility: Study Team

Description:

- Protocol has gone through its entire life cycle, no more subjects are in treatment or on follow-up and the IRB considers the study as completed.
- The expected outcome has been achieved.
- No further action is expected on this protocol.
- Once you have the IRB Study Closure documented in OnCore, you can mark the study as closed with the IRB.

ABANDONED

Status Group: Completed

Trigger: [Abandon] button at PC Console > Status

Responsibility: Study Team

Description:

- The protocol was abandoned **prior to ever being opened to accrual**.
- Before opening a study to accrual, a trial might be abandoned due to safety concerns, low accrual, drug availability, insufficient staff, or loss of funding.
- A protocol can only be marked **Abandoned** before the study is opened for accrual.
- No further action on this protocol is expected.
- The **Abandon** button is displayed until a protocol status has been changed to **Open to Accrual**.
- The **Undo Abandon** button is displayed once a protocol has been **Abandoned**.
- A protocol is removed from **Abandoned** status by clicking **Undo Abandon;** the protocol reverts to its previous status.

TERMINATED

Status Group: Completed

Trigger: [Terminate] button at PC Console > Status

Responsibility: Study Team

Description:

- The protocol was terminated **after the study was opened to accrual.**
- A status of **Terminated** indicates that the protocol ended prior to completing the expected outcome.
- A trial might be terminated due to safety concerns, low accrual, drug availability, insufficient staff, loss of funding.
- No further action on this protocol is expected.
- The **Terminate** button is displayed once a protocol status has been changed to **Closed to Accrual**.
- The **Undo Terminate** button is displayed once a protocol has been **Terminated**.
- A protocol is removed from **Terminated** status by clicking **Undo Terminate;** the protocol reverts to its previous status.