

Protocol Statuses in OnCore

Which role updates the status?

Study Coordinator or Research Assistant or Regulatory



Basic protocol information has been entered in OnCore

- The IRB has reviewed and approved the protocol
- IRB approved documents are uploaded in OnCore

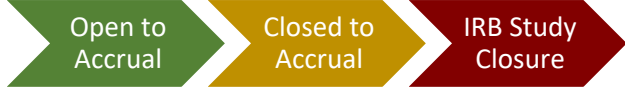
The budget and contract are fully executed

The following are complete:

- Site initiation visit
- Delegation of Authority log
- Protocol related training and logs
- Lab preparation
- Investigational drug/device is available, etc.

- No pending Regulatory items or submissions
- Notification from Sponsor to Open

Clinical Trials Manager or Study Coordinator



- Manager reviews
- Subjects can be added to the study

- Accrual target has been met
- Subjects can no longer be added to the study
- Current subjects may be in treatment or follow-up
- Data is being analyzed

- Sponsor ends the study
- No further action on this protocol is expected



- *Before* opening to accrual, a sponsor may announce the protocol is ON HOLD
- A status of ON HOLD indicates the protocol is *temporarily* stopped
- When the ON HOLD status is changed to OFF HOLD, the protocol reverts back to its previous status
- The ON HOLD status is only available *before* a protocol is opened for accrual



- *Before* opening a study to accrual, a trial might be ABANDONED due to safety concerns, low accrual, drug availability, loss of funding, etc.
- A study can only be ABANDONED prior to OPEN to ACCRUAL

PROTOCOL IS OPENED FOR ACCRUAL



- After Opening a protocol to accrual, a protocol can be SUSPENDED to prevent new subjects from being added
- A status of SUSPENDED indicates that enrollment will potentially resume in the future
- Undo-Suspend will re-open the study to accrual



- Study retention time period has been met.
- Study has been destroyed