

Protocol Lifecycle Checklist

Study Start-Up

PC Console>Main

- Details tab - Accrual Information (Goals), Anticipated Completion Dates, NCT number
- Management tab - IRB number, Internal Account Number, NCI number (MCC only)
- Staff tab - Primary Study Contact and PI roles are mandatory, add staff as needed
- Sponsor tab - Principal Sponsor and Funding source identified
- Annotations tab - Verify special topics and populations

PC Console>Reviews tab

- Enter Initial IRB Approval
- Add documents-
 - Protocol for SAO, SMO or FSM
 - ICF for SMO or FSM (SAO if applicable)
 - IRB Approval Letter and Summary of Changes (MCC only)

PC Console>Status tab

- Enter Regulatory Sign off (Clinical sign off and Finance sign off, MCC only)
- Use On Hold and Off Hold statuses as needed
- Enter Open [to Accrual] or Abandon[ed]

Study Maintenance

For SAO protocols: PC Console>Accrual tab

- Enter accruals individually to capture limited demographics (minimum quarterly)

For SMO and FSM protocols: CRA Console/Subject Console

- Add subjects to study and enter subject milestones (1 business day)
- Check in subject visits (minimum monthly)
- Use Calendar Build Notes (PC Console>Docs/Info tab) for reference to see protocol specific calendar segment triggers

Coverage Analysis Console

- Use billing grid to guide Research Billing Review in Epic (if applicable)

PC Console>Reviews tab

- Enter IRB reviews as needed (ex. Modification Request, Continuation Reviews)
- Submit amendments to CRSO (recommend at the same time you submit to IRB)
- Any new protocol version or ICF is mandatory (SMO and FSM)

PC Console>Staff Tab

- Update staff as changes occur, add stop dates, as appropriate

CRA Console (FSM)

- Up-version subjects to new calendar versions, as needed

PC Console>Status tab

- Verify with clinical team that all subjects are added in OnCore before closing to accrual
- Update protocol status to Close to Accrual when enrollment closes
- Use Suspend, as needed

PC Console>Reviews tab

- Continue to Update IRB reviews, Continuation/Modification Reviews, as needed
- Enter IRB review reason Study Closure when appropriate

Study Closure

PC Console>Status tab

- Update status to IRB Study Closure or Terminated, as applicable
- Verify with clinical team that all subjects are Off Study, Withdrawn, Expired or Not Eligible (SMO and FSM)

PC Console>Main>Details

- Enter Actual Completion dates

PC Console>Annotations

- Enter Financial Closure Date

Abbreviations:

CRA	Clinical Research Associate
CRSO	Clinical Research Support Office
FSM	Full Subject Management
ICF	Informed Consent Form
IRB	Institutional Review Board
MCC	Markey Cancer Center
NCI	National Cancer Institute
NCT	National Clinical Trial
PC	Protocol Coordinator
PI	Principal Investigator
SAO	Summary Accrual Only
SMO	Subject Milestones Only