OnCore Status Workflow Pre-Open to Accrual (Non-Cancer Center)

Responsible Party:
Office of Clinical Research

Notifications:
None

Status automatically assigned when a protocol is initially entered into OnCore.

Responsible Party:
Study Team

Notifications:
OCR Signoff reminder to Office of Clinical Research

Status automatically populates when the Initial IRB Approval is entered by study team.

Responsible Party:
Office of Clinical Research

Notifications:
Research Unit Signoff reminder to Study Site Contact, Budget Contact and Central Admin

Signoff completed once coverage analysis has been finalized by the Office of Clinical Research and the final contract and informed consent have been reviewed for consistency where applicable.

Responsible Party:
Study Team

Notifications:
Open to Accrual reminder to Office of Clinical Research

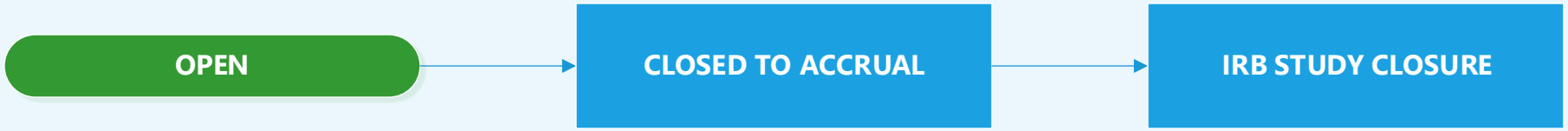
Signoff completed once all required reviews are complete, sponsor authorization obtained and the study team is fully prepared to begin seeing patients. OnCore calendar and budget should also be reviewed where applicable as well as request to use Summary Accrual.

Responsible Party:
Office of Clinical Research

Notifications:
Open to Accrual notice to Study Site Contact, Budget Contact and Central Admin

Completed ASAP after Research Unit Signoff occurs. Allows for centralized RPE push from OnCore to PowerTrials by the Office of Clinical Research. Calendar release and final OnCore QA is also completed at this time.

OnCore Status Workflow Post Open to Accrual (Non-Cancer Center)



Responsible Party:
Office of Clinical Research

Notifications:
Open to Accrual notice to Study Site Contact, Budget Contact and Central Admin

Open to Accrual Date is the date on which the institution is open to accrual/enrollment. This means all required reviews are complete, sponsor authorization obtained, and the research group is fully prepared to begin seeing patients. This date may be on or after the IRB Initial Approval Date.

Responsible Party:
Study Team

Notifications:
Closed to Accrual notice to Study Site Contact, PowerTrials Study Contact, PowerTrials Creator and Central Admin

Status selected when the protocol accrual target has been reached and/or the study is no longer enrolling subjects. Subjects may still be active, results collected and recorded and data analyzed.

Responsible Party:
Study Team

Notifications:
IRB Study Closure notice to Study Site Contact, PowerTrials Study Contact, PowerTrials Creator and Central Admin

Status selected to indicate that a protocol ran its intended course and/or the expected outcome was achieved. This status may only be selected when no further action is required on the study and it is officially closed with the IRB. The status can also be used to indicate a study has expired and will not be reapproved by the IRB. Before placing a study in this status, all subjects listed as active in OnCore should be placed in Off Study status.