

Non-Cancer Center Protocol Status Workflow

PRE-OPEN TO ACCRUAL

	RESPONSIBLE PARTY	NOTIFICATIONS	
New	OCR	None	Status automatically assigned when a protocol is initially entered into OnCore.
IRB Initial Approval	Study Team	OCR signoff reminder to Office of Clinical Research	Status automatically populates when the initial IRB approval is manually entered by the study team or is pulled into OnCore.
OCR Signoffs	OCR	Research unit sign off reminder to study site contact, budget contact and central admin.	Sign-off completed once the OCR has finalized coverage analysis and the final contract and informed consent have been reviewed for consistency, where applicable.
Research Unit Sign Offs	Study Team	Open to Accrual reminder to OCR	Sign-off completed once all required reviews are final, sponsor authorization is obtained, and the study team is fully prepared to begin seeing patients. OnCore calendar & budget should also be finalized, where applicable, and summary accrual requested, if needed. Sign-off also signifies coverage analysis summary is approved by PI or delegate.

OPEN	OCR	Open to Accrual notice sent to Study Site Contact, Budget Contact, Central Administrator, and Data Coordinators listed in OnCore.	Open to Accrual Date is the date on which the institution is open to accrual/enrollment. It is completed ASAP after Research Unit Signoff occurs. At the time of Opening, the Office of Clinical Research integrates the study with Cerner PowerTrials, releases the OnCore Calendar for use, and completes a final OnCore QA.
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POST-OPEN TO ACCRUAL

Closed to Accrual	Study Team	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.
IRB Study Closure	Study Team	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.