

OnCore Protocol Status Alerts

Leadership Brief | Draft Plan

Purpose: Provide a quick view of the proposed notification and escalation process for studies that remain in an OnCore status beyond established timeframes.

Leadership takeaway

The process uses time-based alerts, a defined response window, and status changes when records are not updated. Most pre-activation statuses move to Abandoned; later-stage statuses may move to Suspended, Terminated, or IRB Study Closure.

What the process is designed to do

- Improve the accuracy of OnCore protocol records and reduce studies remaining indefinitely in outdated statuses.
- Give study teams a clear opportunity to confirm activity or update the record before an administrative status change.
- Create a consistent escalation path based on the study status, length of time in that status, and whether the team responds.
- Document enrollment-monitoring follow-up for non-cancer studies in the OnCore Reviews tab.

Process Overview

1. Identify	2. Notify	3. Allow response	4. Resolve or escalate
Studies remain in a status beyond established timeframes.	Appropriate stakeholders are notified and asked to review the study's current status.	Study teams confirm activity, provide updates, or identify barriers to progress.	Records are updated, monitoring continues, or the study advances to the appropriate administrative or closure pathway.

Status-Based Alert Summary

This table Summarizes alert triggers, accountable recipients, expected responses, and escalation paths for unresolved OnCore protocol statuses.

Cancer Center studies will follow the same OnCore alert schedule, with messaging tailored to Cancer Center processes.

OnCore status	Trigger	Primary recipients	Expected response	If unresolved
New	6+ months	CRMS, APM, Coverage Analyst, site contact, PI	Confirm the study is active or provide an update within 10 days.	Move to On Hold if active but delayed; otherwise Abandoned.
On Hold	6+ months; final action at 12+ months	Site contact and PI; broader operational recipients for final action	Provide an update within 10 days. Monthly reminders may continue.	Abandoned for no response or no progress; automatic action at 12+ months.
SRC Approval	6+ months	SRC, PI, study team	Notice sent to Cancer Center.	Notice states that length of time in status. No follow-up messaging.
IRB Initial Approval	6+ months	CRMS, APM, Coverage Analyst	Enter OCR Signoff, abandon, or request On Hold.	Abandoned if staff do not respond or update.
Account Signoff	6+ months	Site contact and PI	Enter Research Unit Signoff, abandon, or request On Hold within 10 days.	Abandoned if no response or update.
OCR Signoff	6+ months	Site contact and PI	Enter Research Unit Signoff, abandon, or	Abandoned if no response or update.

OnCore status	Trigger	Primary recipients	Expected response	If unresolved
			request On Hold within 10 days.	
Research Unit Signoff	6+ months	CRMS, APM, Coverage Analyst	Enter OCR Signoff, abandon, or request On Hold.	Abandoned if staff do not respond or update.
Open to Accrual, zero accruing (non-Cancer Center)	No enrollment update for 12+ months	PI, study team, department POC	Complete a brief enrollment update; follow-up is documented in Reviews. May be referred to PRIMED for Success.	Recruitment review by PRIMED for Success if struggling; Suspended after repeated no response.
Open to Accrual, zero accruing (Cancer Center)	Per PRMS Bylaws	Per PRMS process	Follow PRMS Bylaws.	Per PRMS process.
Closed to Accrual	5+ years	PI and study contact	Confirm active status or complete closeout within 30 days.	Terminated or IRB Study Closure, based on available information.
Suspended	6+ months; escalation at 12+ months	PI and study contact; CRMS and review team as needed	Reopen or close the study; monthly notices may continue for 6 more months.	Terminated after repeated no response; review-team evaluation after 12+ months when the team has responded.