

OnCore Communication Memo

Memo #: 12 – Multi-Site Checklist Go-Live

To: Research Managers, Budget, Regulatory Staff and CTO-AD

From: System Administrator

Effective Date: April 7, 2014

Purpose: The Multi-Site Checklist view only capability has been enabled in OnCore for specific staff to know at what point multi-site IIT's are in the approval process.

Notes: Found under: PC Console>Status>Checklists OR Protocols>Checklist.

The screenshot displays the OnCore PC Console interface for protocol RTOG-0839. The top navigation bar is dark red with the text '★ PC Console'. Below this, a header section contains protocol information: 'Protocol No.: RTOG-0839', 'Library: Oncology', 'PI: Gore, Elizabeth', 'Protocol Target Accrual: 97', 'Accrual To Date: 3', and 'Protocol Stat'. Below the header, a summary row shows 'RC Total Accrual Goal (Upper): 8'. The main content area is divided into a left sidebar and a main table. The sidebar has a 'Select Protocol' dropdown menu and a list of menu items: 'Main', 'Treatment', 'Institution', 'Accrual', 'Status', and 'Reviews', each with a right-pointing arrow. The main table has two tabs: 'Status' and 'Checklists'. The 'Checklists' tab is active, showing a table with columns 'Checklist' and 'Info'. The 'Checklist' column contains several blue hyperlinks: 'Beacon', 'Budget', 'CC-Managers-New Trial', 'Multi-Site', 'Regulatory', 'Regulatory-Amendments', and 'Regulatory-CPRs'. The 'Info' column contains corresponding status information. The 'Multi-Site' link is circled in red.

Checklist	Info
Beacon	
Budget	
CC-Managers-New Trial	
Multi-Site	
Regulatory	Cooperative Group Activation Date (11/30/2010) In Progress
Regulatory-Amendments	Reg Notified Appropriate Staff (09/30/2013) Complete
Regulatory-CPRs	CPR Research Manager/CRC Notified of Completion (09/17/2013) Complete

CC-Managers-New Trial	Checklist Item	Target Date	Not Applicable	Communications	
				Communication Date	Comments
Multi-Site	Received notice for review of Multi-Site Activation				
Regulatory	Feasibility Assessment (IND vs. Non-IND process)				
Regulatory-Amendments	Grant/Funding received				
Regulatory-CPRs	Grant/Funding approved				
PC Console	Budget for Multi-Site approved				
	Subcontract Submitted to MCW CGO				
	Subcontract Approved by MCW CGO				
	Statement of Work Submitted to MCW CGO				
	Statement of Work Approved by MCW CGO				
	Financial Documents Submitted to Participating Site				
	Financial Documents Approved by Participating Site				
	OnCore Feasibility Review				
	OnCore Feasibility Approval				
	Statistician Consult and Recommendation				
	eCRF/ Calendar Built and activated				
	Data Management Process Approved				
	IRB Operational Plan Submitted to CTO Reg				
	IRB Operational Plan approved by MCW IRB				
	MCW IRB Approved Documents sent to Site				
	Participating Site approved IRB Documents received				
	Participating Site approved IRB Documents approved				
	PI approval of Operational Plan				
	Participating Site Approved for Activation				
	Participating Site notified of Activation				
	Amendments/Deviations sent to by Participating Site				
	Amendment approved by Participating Site				
	CPR received by Participating Site				
	MCW IRB Approval of Ongoing Regulatory				
	SAE's Received by Participating Site				
	Protocol Deviations Received by Participating Site				