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.

CC-Managers-New Trial

Multi-Site

Regulatory

Regulatory-Amendments

Regulatory-CPRs

PC Console

Checklist Item	Target Date	Not Applicable	Communications	
			Communication Date	Comments
Received notice for review of Multi-Site Activation				
Feasibility Assessment (IND vs. Non-IND process)				
Grant/Funding received				
Grant/Funding approved				
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				