

OnCore Communication Memo

Memo #: 18 – Removal of Regulatory Sign-Off for Protocol Activation

To: All Regulatory Staff, Research Managers, CTO-AD

From: System Administrator

Effective Date: October 23, 2014

Purpose: Removal of the Regulatory Sign-Off button for protocol activation

Notes: Starting immediately, protocols will no longer require Regulatory Staff sign-off in order for the study to move to the Opened to Accrual status. Other than SRC Approval and IRB Initial Approval, the only other sign off that is required is the Research Manager-DTL Signoff. Instead, a new checklist has been created to capture all dates related to Study Activation tasks, including, among others, the key Regulatory tasks. This Study Activation checklist will be completed and maintained by the Research Managers.

Select Protocol
Type here to search

Main »
Treatment »
Institution
Accrual
Status »
Reviews »

Status Checklists ClinicalTrials.gov

Protocol Status History

Status Date	Status	Initiator	Change Reason	Comments	Last Changed By
05/28/2014	IRB INITIAL APPROVAL				Manteufel, Jessica
03/03/2014	SRC APPROVAL	Cancer SRC A			Glich, Katie
02/21/2014	NEW				Manteufel, Jessica

On Hold Research Manager-DTL Signoff Abandon Update

[SRC Submission Form](#) |

Beacon
Budget
CC-Managers-New Trial
Multi-Site
Regulatory
Regulatory-Amendments
Regulatory-CPRs
Study Activation
PC Console

Status:
Comments:

Checklist Item	Target Date	Not Applicable	Communications	
			Communication Date	Comments
FRC Final Approval				
SRC Approval Date				
DSMC Initial Approval Date (IIT's only)				
Fully Executed Contract Date				
Finalized Budget Date (IIT's only)				
IRB Approval Date				
OCRICC Approval Date				
Beacon Release Date				
Credentialing - Activation				
ClinicalTrials.gov Released Date (IIT's only)				
CTSU Registration Status Approved Date				
SIV or Startup Meeting Date				
Site Activation By Sponsor Date				