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.