Instructions for Requesting and Approving New Checklist Item Templates OR Changing Existing Checklist Item Templates in CTMS

Checklist Item Template Types

CTMS houses standard checklist item templates for the following visit types:

- SSV
- SIV
- SSV/SIV Combination
- PMV
- COV

Control/Approval Process for New or Changes to Standard Templates

The authorized Clinical Operations individual submits the following to the DCRI Service Desk requesting a new standard checklist item template, or changes to an existing standard checklist item template(s).

- Signed CTMSR.
- The list of requested changes via an Excel document.
- Written documentation of approval from the Clinical Operations Director or designated Assistant Director (AD). This approval is required before any changes are made.

Control/Approval Process for Protocol Specific Templates

The Project Lead (PL) or Lead CRA submits the following to the DCRI Service Desk requesting changes to a standard checklist item template to make it Protocol specific, OR requesting a new Protocol specific template which will not be based on the standard DCRI template.

- Signed CTMSR.
- The list of requested changes via an Excel document.
- Written documentation of approval from the appropriate Clinical Trial Manager (CTM) or Mega Trials Approver. This approval is required before any changes are made.

NOTE: It is the CTM’s responsibility to ensure the requested revisions are consistent with the applicable Standard Operating Procedure (SOP) and Clinical Monitoring Plan (CMP). The CTM should consult DCRI QA/RC as needed.