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.