

CTMS DEG Review Checklist

Recommended Use:

It is recommended that prior to the DEG being submitted to the DCRI Service Desk for attachment in CTMS, the DEG be reviewed against this checklist in order to confirm that all of the key components have been included and it is consistent with the applicable Activity Plan(s).

Area	Item	Review
General	Current Version of DEG Template	Current version of the DEG Template has been used
General	Section Numbers	Section numbers still correspond with the table of contents
Title Page	Bookmarks	Ensure Bookmarks for CTMS Acronym, Template Version and Effective Date are in place
Title Page	Author and Approver	Names and Dates are completed
2.1	Site Number Format & Regions	A sample of of the Site # , as well as all Regions are included
2.2	Activity Plan(s)	Names of the Activity Plan(s) are listed - If multiple Activity Plans will be used, instructions are also included
2.3	Account Affiliations	IRB is required and must be included
2.6	Milestones	At a minimum, all of the Milestones in the Activity Plan must also be listed here
2.8	Training	At a minimum all of the Training in the Activity Plan must also be listed here
2.9	Documents	Refer to section 4 below
2.10	Other Requirements	At a minimum all of the other requirements that are in the Activity Plan must also be listed here
3.2	Subjects	Import or Manual enrollment information is included
4	Document & Version Date Definitions	All Documents in the Activity Plan must also be listed here and instructions for Version Date, Exp Date, Status Instructions and Additional Instructions and Comments should also be included here