


Letter of Amendment Flowchart


Request for the use of a Letter of Amendment (LoA)



- ◆ The Protocol Team requests approval for use of a LoA by sending an email to the DAIDS Regulatory Support Center (RSC) (Regulatory@tech-res.com, copy (CC): CSIO@tech-res.com). In the email the Protocol Team should either:
 - Describe the changes to be made using a LoA
 - Attach a draft LoA
- ◆ The DAIDS RSC sends the Team's request for the use of a LoA to the DAIDS Regulatory Affairs Branch (RAB).
- ◆ The DAIDS RSC notifies the Protocol Team of DAIDS RAB's decision on the use of a LOA and any changes that may be required.




DAIDS Medical Officer (MO) Review and Sign-off



- ◆ The Protocol Team submits the revised document to the DAIDS RSC (Regulatory@tech-res.com, CC: CSIO@tech-res.com).
- ◆ The DAIDS RSC sends the LOA to MO for review and sign-off.
- ◆ The DAIDS RSC notifies the Protocol Team of the MO's review decision and any changes that may be required; the MO's sign-off form is attached to the e-mail.



Final DAIDS RAB Sign-off



- ◆ The Protocol Team submits the final LoA to the DAIDS RSC (Regulatory@tech-res.com, CC: CSIO@tech-res.com).
- ◆ The DAIDS RSC sends the LOA to DAIDS RAB for review and sign-off.
- ◆ The DAIDS RSC notifies the Protocol Team of DAIDS RAB's approval decision using one of the mechanisms listed below:



Email notification of RAB Approval of the Letter of Amendment as written (Non-IND study)



Email notification of the submission of the Letter of Amendment to the Food and Drug Administration (IND Study)



Email acknowledgement of DAIDS Medical Officer Approval for the Letter of Amendment (Non-DAIDS Held Study)

The Final Approved Letter of Amendment is distributed by the Operations (Ops) Center to the sites for implementation.