

SOPs included in the Manual of Standard Operating Procedures (M-SOP) 7.0
SOP 01-01 <i>Essential Records Submission for Sponsor's Trial Master File</i> (v10.0)
SOP 01-02 <i>Study Initiation Meeting</i> (v7.0)
SOP 01-03 <i>Accruing LAO and AO Activation</i> (v7.0)
SOP 02-01 <i>Reporting Serious Adverse Events</i> (v7.0)
SOP 02-02 <i>Reporting Protocol Deviations</i> (v6.0)
SOP 02-03 <i>System Variable Attribute Report and Electronic Case Report Form Development</i> (v6.0)
SOP 02-04 <i>Participant Recruitment, Retention, Adherence, and Reporting Requirements</i> (v7.0)
SOP 02-05 <i>Policy on Standard Operating Procedures</i> (v6.0)
SOP 02-06 <i>Biospecimen Submission Requirements</i> (v6.0)
SOP 02-07 <i>Unblinding Participants</i> (v5.0)
SOP 03-02 <i>Site Preparations for Quality Assurance Audits</i> (v5.0)
SOP 03-03 <i>LAO Oversight Activities</i> (v7.0)
SOP 04-01 <i>Instructions for Accruing LAO and AO Closeout</i> (v4.0)
SOP 04-02 <i>Study Closeout</i> (v2.0)

All LAO staff need to review and sign off on the M-SOP as part of the oversight that they provide for their accruing LAOs and AOs. Accruing LAO and AO staff that are listed on the *DCP Delegation of Tasks Log (DTL)* with the task codes listed below are required to review and sign off on the M-SOP as well. The M-SOP does not apply to the other DTL task codes.

DCP Delegation of Tasks Log task codes that require M-SOP sign-off
1. Agent/Intervention Prescribing: Responsible for writing an order for a patient that is an agent or intervention.
2. Site Principal Investigator (PI): Investigator at the site responsible for signing the DTL for a given protocol, and with overall responsibility for the study conduct at the site.
3. Consenting Person: Person having responsibility for consent.
5. Eligibility Assessments: Verification of eligibility.
6. End Point Assessments: Assess study end points.
7. Enrolling Person/Treating Investigator: Investigator having responsibility for subject treatment (aka, Enrolling investigator).
8. History and Physical (H&P) Assessments: Conducts physical exam and assessments.
11. Patient Screening/Recruiting: Responsible for screening and recruiting of subjects.
12. Primary Study/Site Contact: The point of contact for the study.
13. Rave CRA: Rave write access; responsible for data management and uploads of Central Monitoring documents; and using Rave CTEP- AERS safety reporting tools.
14. Rave Investigator: Investigator assigned to sign-off on the CRFs in Rave.
15. Regulatory Contact: Site staff responsible for regulatory submissions and maintaining essential records.
17. Source Documentation Completion: Responsible for collecting data on study-related assessments.
18. Study-related Interventions: Responsible for coordinating and/or administering study-related interventions and procedures.
19. Toxicity Assessment: Assesses adverse events.

