SOPs

- 101-S02 Document Control SOP
- 101-S04 Change Control SOP
- 101-S05 Providing OSRO Documents to Collaborators SOP
- 103-S01 Training Program SOP
- 104-S01 Corrective and Preventive Action (CAPA) System SOP
- 104-S02 Clinical Protocol Non-Adherence System SOP
- 104-S03 OSRO Internal Deviation System SOP
- 202-S03 Evaluation of Protocol Amendments for FDA Notification Prior to Implementation SOP
- 203-S01 Essential Regulatory Documents Required for a Clinical Study SOP
- 204-S01 Emergency Use of Qualified Non-NIH Facility SOP
- 205-S01 Clinical Site Monitoring Plans - Development and Maintenance SOP
- 301-S01 Evaluating Serious Adverse Events from Clinical Trial Study Interventions SOP
- 301-S02 Serious Adverse Event Reconciliation SOP
- 401-S01 Financial Disclosure by Clinical Investigators SOP
- 410-S01 Determination of Final Clinical Study Report Type SOP
- 501-S01 Investigational Product Certificates of Analysis SOP
- 501-S02 Investigational Product Labels SOP
- 501-S03 Investigational Product Quality Agreements and Product Agreements SOP
- 501-S04 Investigational Product Unique Ingredient Identifier SOP