CRSO SOP Development Table

100. CRSO Operations

SOP Number/Version	SOP Title	Status
101.3	CRSO SOP on SOPs	Revised September 13, 2021

200. CRAU Operations

SOP Number/Version	SOP Title	Status
201.1	Development and Management of Standard Operating Procedures	Planned
202.1	Establishing and Maintaining CRAU Charters	Planned
203. 1	CRAU Administrative Processes	Planned

300. Research Operations

SOP Number/Version	SOP Title	Status
301.1	Protocol Development	Planned
302.1	Feasibility Assessment	In development
303.1	Clinical Research Management Systems	Planned
304.1	Epic	Planned
305.1	Electronic File Organization for Research Records	Planned
306.1	Study Start-up Process	Planned
307. 1	Protocol Adherence	Planned
308. 1	Study Close-out	Planned

400. Investigators and Study Team

SOP Number/Version	SOP Title	Status
401.1	Investigator Responsibilities	In development
402.1	Sponsor-Investigator Responsibilities	In development
403.1	Research Team Responsibilities	Planned
404.1	Establishing a Clinical Research Team	Planned
405.1	Hiring and Onboarding Study Staff	Planned
406.1	Personnel Training and Development	Planned

500. Research Participants

SOP Number/Version	SOP Title	Status
501.1	Obtaining and Documenting Informed Consent from Adult Research Participants	Coming soon!
502.1	Informed Consent for Minor Research Participants	Planned
503.1	Participant Eligibility	Planned
504.1	Communicating with Study Participants	Planned
505.1	Participant Visits and Assessments	Planned
506.1	Participant Status and Change in Status	Planned

600. Research Sponsors

SOP Number/Version	SOP Title	Status
601.1	Reviewing and completing Confidential Disclosure Agreements (CDA)	Planned
602.1	Reviewing and establishing contracts with study sponsors	Planned
603.1	Communicating with study sponsors	Planned
604.1	Coordinating and participating in monitoring visits	Planned

700. Regulatory Responsibilities

SOP Number/Version	SOP Title	Status
701.1	IRB Submissions	Planned
702.1	Developing the Informed Consent Form	In Development
703.1	Essential Documents Management	Planned
704.1	IND Management	Planned
705.1	IDE Management	Planned
706.1	Institutional Research Requirements and Ancillary Reviews	Planned
707.1	ClinicalTrials.gov Registration and Reporting	Planned
708.1	COI Disclosures and Review	Planned
709.1	Data and Safety Monitoring	Planned
710.1	Adverse Event Management and Reporting	Planned
711.1	Protocol Deviations Management and Reporting	Planned
712.1	External Regulatory Inspections and Audits	Planned

800. Research Data

SOP Number/Version	SOP Title	Status
801.1	Source Documentation	Planned
802.1	Specimen Management	Planned
803.1	Conducting Quality Assurance Reviews	Planned
804.1	Creating and Utilizing Notes to File	Planned
805.1	Record Retention and Archiving	Planned

900. Research Financial Management

SOP Number/Version	SOP Title	Status
901.1	Billing Coverage Analysis (BCA)	Planned
902.1	Clinical Budget Development	Planned
903.1	Tracking Study Finances	Planned
904.1	Payments to Participants	Planned
905.1	Payments to Vendors and Collaborators	Planned