Clinical Research Office Standard Operating Procedures

No.	GENERAL ADMINISTRATION	OWNER	DATE
1.1	Preparing, Maintaining and Training on SOPs	UNM CCC CRO Director / NMCCA Exec Director	12/14/2017
1.2	Responsibilities of the Research Team	UNM CCC CRO Director	12/20/2017
1.3	Training and Education	UNM CCC CRO Director	12/20/2017
1.4	Conflicts of Interest in Research	NMCCA CRM	3/19/2018
1.5	Investigator and Investigative Site Requirements	NMCCA Exec Director	3/19/2018
1.6	Cooperative Group Participation	NMCCA Exec Director	3/19/2018
1.7	NMCCA New Study Process	NMCCA Exec Director	3/19/2018
	STUDY START UP		
2.1	Assessing Protocol Feasibility	NMCCA CRM	3/19/2018
2.2	PreStudy Site Visit (PSSV)	NMCCA CRM	3/19/2018
2.3	Site Initiation Meetings and Visits	NMCCA CRS	12/19/2017
2.4	Study Activation	NMCCA CRS	12/19/2017
2.5	Completing an FDA Form 1572	NMCCA CRS	12/19/2017
2.6	Submitting a New Study Application to IRB	NMCCA CRS	12/19/2017
2.7	Federally Required Website Registration	Assistant Director of Quality Assurance, Monitoring, and Training	3/19/2018
2.8	Protocol Review and Monitoring Committee	NMCCA CRM	3/19/2018
2.9	Investigator Initiated Study Management	Assistant Director of Quality Assurance, Monitoring, and Training	3 /28/2018
	PROJECT MANAGEMENT		
3.1	Interactions with Institutional Review Boards	NMCCA CRS	12/19/2017
3.2	Clinical Subject Records	NMCCA CRM	12/18/2017
3.3	Monitoring Visits	UNM CCC Clinical Operations Manager, NMCCA CRM	3 /28/2018
3.4	Study Termination (Close Out) Visit	NMCCA CRS & UNM CRS	3/19/2018
3.5	Investigational Drug Accountability, Storage, Dispensing and Return	Research Pharmacist	3/22/2018
3.6	Handling of Amendments and Revisions	NMCCA CRS	11/14/2017
3.7	Electronic Correspondence with the HRPO and GCRC	NMCCA CRS	12/21/2017
3.8	Long Term Storage	NMCCA CRM	3/19/2018
3.9	External Adverse Events	NMCCA CRS	3/19/2018
	SUBJECT MANAGEMENT		
4.1	Informed Consent - Development and Implementation	NMCCA CRS	11/14/2017
4.2	Subject Recruitment and Eligibility	NMCCA CRM	12/18/2019
4.3	Subject Management While on Study	NMCCA CRM	12/18/2017
4.4	Adverse Event Reporting	Assistant Director of Quality Assurance, Monitoring, and Training	12/20/2017
4.5	Specimen Collection, Handling and Disposal	UNM CCC Clinical Research Operations Manager	3 /28/2018
4.6	*ARCHIVED*		
4.7	*OPEN*		
4.8	Protocol Deviation Reporting and Prevention	NMCCA CRM	12/18/2017
4.9	Emergency Use of An Unapproved Investigational Drug or Agent	NMCCA Medical Director	3 /28/2018
	DATA MANAGEMENT		
5.1	Evelos Disaster Plan	Velos Database Manager	3/19/2018
5.2	Evelos Accounts and Passwords	Velos Data Manager	3/19/2018
5.3	Evelos Case Report Form Development and Completion Monitoring	UNM CCC Clinical Research Operations Manager	12/19/2017
	QUALITY ASSURANCE		
6.1	Quality Asssurance Program	Assistant Director of Quality Assurance, Monitoring, and Training	12/20/2017
6.2	Internal Audit of NCTN and IIT Clinical Trials	Assistant Director of Quality Assurance, Monitoring, and Training	12/20/2017
6.3	NCTC Triennial Group Audits	Assistant Director of Quality Assurance, Monitoring, and Training	12/20/2017
6.4	Preparing for an FDA Audit	Assistant Director of Quality Assurance, Monitoring, and Training	12/20/2017
6.5	Assuring Subject Safety - Investigator Initiated Trials	Assistant Director of Quality Assurance, Monitoring, and Training	12/20/2017
6.6	Making a Hand Written Error Correction	Assistant Director of Quality Assurance, Monitoring, and Training	3/19/2018
	BUDGET MANAGEMENT		
7.1	Research Patient Billing Procedures	Program Manager, CRO Billing	3/19/2018