CLINICAL RESEARCH SOP TABLE OF CONTENTS

	GENERAL ADMINISTRATION
UTRGV GA-101	Development and Maintenance of Standard Operating Procedures
UTRGV GA-102	Access and Use of Protected Health Information Preparatory to Research
UTRGV GA-103	UTRGV Research Credentialing – Under Development
UTRGV GA-104	Scope of Practice
UTRGV GA-105	Investigator Responsibility for Study Team Training and Documentation
UTRGV GA-106	Transfer of Sponsor-Investigator Initiated FDA Regulated Studies
UTRGV GA-107	Investigator Training – Under Development
UTRGV GA-108	Investigator-Initiated Research – Under Development
UTRGV GA-109	Departing Investigators
	REGULATORY AFFAIRS
RA-201	Regulatory Documentation
RA-202	IRB Submissions – Under Development
RA-203	Document Control
RA-204	Adverse Event Reporting
RA-205	Use of Florence for Electronic Records and Electronic Signatures
RA-206	Florence End User Training
	PROJECT MANAGEMENT
PM-301	Study Feasibility – Under Development
PM-302	Site Qualification Visit
PM-303	Site Initiation Visit
PM-304	Study Monitoring Visits
PM-305	Study Closeout for Sponsored Clinical Research
PM-306	Registration of Clinical Trials in ClinicalTrials.gov
PM-307	Results Reporting of Clinical Trials in ClinicalTrials.gov
	SUBJECT MANAGEMENT
SM-401	Subject Screening, Recruitment and Eligibility

SM-402	Informed Consent Process
SM-403	Study Visits
SM-404	Protection of Confidential Information
SM-405	Specimen Collection and Management
	DATA MANAGEMENT
DM-501	Case Report Form Completion
DM-502	Source Documentation Standards
DM-503	Research Documentation (Electronic Medical Record) – Under Development
DM-504	Research Record Retention, Archive, and Storage
DM-505	Certified Copies of Research Regulatory Documents
	QUALITY ASSURANCE
QA-601	FDA Inspections
QA-602	Corrective and Preventive Action (CAPA) Plan
QA-603	Remote EMR Access for Monitors Auditors – Under Development
QA-604	Equipment Registration, Maintenance and Calibration
QA-605	Temperature Monitoring
	FINANCIAL MANAGEMENT
FM-701	Coverage Analysis
FM-702	Management of Clinical Research Expense Invoicing -Under Development
	Glossary of Terms