

VCU/VCU Health Clinical Research SOP Operational Guidelines



VCU/VCU HEALTH CLINICAL RESEARCH STANDARD OPERATING PROCEDURES

SOP No.: CR-AD-000

Status: Final

Version Date: 07/01/2024

Effective Date:

Section 100 – Administrative

CR-AD-100: VCU/VCU Health Clinical Research SOP Operational Guidelines

CR-AD-105: Investigator Responsibilities

CR-AD-110: Participating Investigator Qualification

CR-AD-115: Study Feasibility

CR-AD-120: Clinical Research Management System

Section 200 – Start up

CR-ST-200: Clinical Trial Registration and Reporting

CR-ST-205: Investigator Conflicts of Interest

CR-ST-210: Contracts for Externally-Sponsored Clinical Research

CR-ST-215: Clinical Trial Registration and Reporting

CR-ST-220: Form FDA 1572

CR-ST-225: Pre-Study Site Qualification Visit

CR-ST-230: General Research Staff Training and Clinical Permissions

CR-ST-235: Site Initiation Visit

CR-ST-240: Study-Specific Staff Education and Training

Section 300 – Regulatory

CR-RE-300: Adverse Event and Management and Problem Reporting

CR-RE-305: Coordination of External Regulatory Audits

CR-RE-310: Data Safety Monitoring

CR-RE-315: Informed Consent

CR-RE-320: Institutional Biosafety Committee

CR-RE-325: IRB Submissions and Communications

CR-RE-330: Participant Research Complaints or Concerns

CR-RE-335: Protecting Confidential Information

CR-RE-340: Protocol Deviations and Violations

CR-RE-345: Radiation Safety Committee

CR-RE-350: Sponsor-Investigator (IND/IDE) Applications

CR-RE-355: Sponsor Monitor Visit

CR-RE-360: Study-Specific Communications

Section 400 – Investigational products

CR-IP-400: Investigational Drug Management and Investigational Drug Transfer to Satellite Pharmacies

CR-IP-410: Investigational Device Management

Section 500 – Conducting clinical studies

CR-CO-500: Blinding – Codes and Code Breaking

CR-CO-505: Case Report Form Compliance

CR-CO-510: Clinical Research Record Management

CR-CO-515: Data Clarification

CR-CO-520: Data Management

CR-CO-525: Delegation of Authority
CR-CO-530: Electronic Data Capture Systems
CR-CO-535: Enrollment on Ancillary Studies
CR-CO-540: Essential Documents Maintenance
CR-CO-545: Participant Status and Change of Status
CR-CO-550: Participant Visits and Assessments
CR-CO-555: Record Retention and Archiving
CR-CO-560: Screening and Recruiting Research Participants
CR-CO-565: Source Documentation
CR-CO-570: Human Biological Specimen Collection, Handling, and Shipping
CR-CO-575: Study Interim Data Analyses and Reports
CR-CO-580: Transfer of Participants Between Institutions
CR-CO-585: Use of Notes to File
Section 600 – End of study and closeout
CR-EN-600: Study Completion and Study Closure
CR-EN-605: Study Suspension, Early Termination, and Early Closure