

VCU/VCU Health Clinical Research SOP Operational Guidelines



VCU/VCU HEALTH CLINICAL RESEARCH STANDARD OPERATING PROCEDURES

SOP No.: CR-AD-000.1

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The SOPs displayed in red text are pending or under review.

Section 100 – Administrative

CR-AD-100.5: VCU/VCU Health Clinical Research SOP Operational Guidelines

CR-AD-105.3: Investigator Responsibilities

CR-AD-110.4: External Qualification

CR-AD-115.4: Study Feasibility

CR-AD-120.4: Clinical Research Management System

Section 200 – Startup

CR-ST-200.3: Clinical Trial Registration and Reporting

CR-ST-205.4: Investigator Conflicts of Interest

CR-ST-210.3: Agreements for Externally-Sponsored Clinical Research

CR-ST-215.3: Coverage Analysis

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-300.3: Adverse Event and Management and Problem Reporting

CR-RE-305: Coordination of External Regulatory Audits

CR-RE-310: Data Safety Monitoring

CR-RE-315.3: 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-400.3: Investigational Drug Management and Investigational Drug Transfer to Satellite Pharmacies

CR-IP-410: Investigational Device Management

Section 500 – Conducting clinical studies

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| 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 |