

CRP Quick Guide

Virginia Commonwealth University (VCU) Resources	
Office of the Vice President for Research and Innovation (OVPRI) https://research.vcu.edu/ OVPRI, Clinical Research Resources https://research.vcu.edu/resources/	• Resources • Integrity and Compliance • Proposals and Awards • Human Research • Training Opportunities • Regulatory Affairs • Investigational Drug Services • HRPP/IRB • Study pipelines for IITs and Industry studies • Study-related templates
VCU Wright Center for Clinical and Translational Research https://ctr.vcu.edu/	• Infrastructure and resources that promote interdisciplinary human health research • Collaborations, support, and CRP training and education
VCU Massey Comprehensive Cancer Center (Massey) & Clinical Trials Office (CTO) https://www.masseycancercenter.org/research/clinical-trials-office/	• Promote and conduct high-quality cancer-relevant human subject research and facilitate the development of cancer-relevant studies
VCU School of Medicine (SOM) https://medschool.vcu.edu/about/departments/	• Includes more than 20 basic health science and clinical / Research departments, affiliate institutes, and centers
Clinical and Translational Science Award (CTSA) https://ctr.vcu.edu/collaborations/ctsa-network/	• Collaborations with 60 CTSA to enhance discoveries into treatments for patients, engage communities in clinical research, and train the next generation

VCU Resources	
VCU RAMS Systems & VIRBs https://research.vcu.edu/rams-systems/ 1. RAMS-AIRS - Activities and Interest Reporting System 2. RAMS-ACUP - Animal Care and Use Program 3. RAMS-ECO -Export Compliance Office 4. RAMS-FORCE - CORE Lab Reservation 5. VIRBs - VCU Institutional Review Board 6. RAMS-SPOT - Sponsored Programs Online Tracking 7. RAMS Reports -Access Various RAMS Reports	• Electronic system for the management of activities provided by the OVPRI • Guidance and Training • Explore VCU Research • Searchable Research Database
VCU & VCU Health: Standard Operating Procedures (SOPs)	• Human Research Protection Program (HRPP), IRB staff, and IRB Member SOPs https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/#d.en.404017 • VCU and VCUHS Clinical Research SOPs https://ctr.vcu.edu/support/clinical-research-sops-new/ • VCU Employee and Facility Use Guidelines for Clinical Research (VCU eID required) https://research.vcu.edu/media/office-of-research-and-innovation/secure/complianceprogram/employee_facility_use_guidelines_clinical_research.pdf Log in with VCU Health eID and Password: • VCU Health Intranet SOPs https://intranet.vcuhealth.org/sites/clinical-research/SitePageModern/94869/standard-operating-procedures • Investigational Drug Services SOPs https://intranet.vcuhealth.org/sites/clinical-research/SitePageModern/79594/investigational-drug-services

VCU Resources	
VCU File Locker https://ts.vcu.edu/askit/university-resources/vcu-filelocker/	• Easily share large files within VCU and outside of the VCU community via email • Temporary and secure storage place to upload, share, request, and download files • Log in with VCU eID and password
VCU Standard DocuSign https://collaborate.vcu.edu/apps/docusign/	• VCU general business use only (i.e., signing an onboarding checklist, etc.) • Electronic signature solution for its legally binding agreements, contracts, and standard VCU business forms • Log in with VCU eID and password
VCU CFR Part 11 Compliant DocuSign Same web link as above, VCU Standard DocuSign Part 11 DocuSign Training https://redcap.vcu.edu/surveys/?s=8KNWMERRPK	• Compliance with Federal Regulation 21 CFR 11 (i.e., eConsent, study documents, PHI-related documents, etc.) • Limited to study documents that relate to FDA-regulated studies • Training must be completed prior to gaining access • VCU eID is required for DocuSign Part 11. VCU Health email accounts cannot be used with Part 11 DocuSign
VCU Procurement Services https://procurement.vcu.edu/i-want-to/pay-an-individual/compensate-a-research-participant/ Prepaid Card Program and Training https://research.vcu.edu/resources/prepaid-card-program/	• VCU Procurement offers services for accounts payable, contracts, travel services, university purchasing, etc. • Research prepaid card program allows studies to pay participants quickly and easily by using a reloadable debit card
VCU TriNetX https://cctr.vcu.edu/support/informatics/cohort-discovery/	• TriNetX is a cohort discovery tool that can be used to conduct feasibility assessments and obtain de-identified data
Collaborative Advance Research Imaging (CARI) https://cctr.vcu.edu/support/clinical-research-service-providers/cari/	• Dedicated research facility for a 3.0 Tesla MRI scanner, mock scanner, interview room, drug screening rooms, and more

VCU Resources	
Veeva SiteVault https://research.vcu.edu/human-research/regulatory-affairs/veeva/ Veeva SiteVault Training Form https://redcap.vcu.edu/surveys/?s=8JP3JDTW8C3RTTPF	• 21 CFR part 11 compliant electronic regulatory system designed for clinical trials • Facilitates signatures, allows external remote monitoring, and is intended to replace paper binders
DEEP6 AI Training and Access https://intranet.massey.vcu.edu/clinical-trials-office/training-education-and-development/deep6-resources/ DEEP6 Access Request Form https://form.jotform.com/220114850732143	• Database that uses inclusion and exclusion requirements as specified for clinical trials in order to potentially match patients and increase patient accruals • Only available to Massey CTO
VCU Health Resources	
VCU Health Intranet: Log in with VCU Health eID and Password https://www.vcuhealth.org/for-employees/	• VCU Clinical Research Intranet • Research Town Hall Meetings / updates • Study Team Resources • Current Studies • Research Units
Investigational Drug Services (IDS) and Vestigo Services https://research.vcu.edu/human-research/ids/ Investigational Drug Services, VCU Health Intranet https://intranet.vcuhealth.org/sites/clinical-research/SitePageModern/79594/investigational-drug-services	• Inventory control, storage, accountability, packaging, labeling, preparation of medications, blinding plans, randomization, and remote monitoring for clinical research • Clinical research internal resources and guides for IDS and clinical research management
VCUHS Language Services (Access by VCU Health Intranet SharePoint) https://vcuhealth.sharepoint.com/sites/language-services/SitePages/Epic.aspx	• Language Interpreter • Sign Language • Combination Text Telephone (TTY) • Sign Language Cards

VCU Health Clinic Scheduling & Testing Centers	
VCU Health Adult Outpatient Pavilion (AOP) https://www.masseycancercenter.org/aop/	• 17 floors, 26 specialty clinics that includes Massey Comprehensive Cancer Center and School of Medicine departments • Laboratory, diagnostic, and imaging services are all in one building
Cellular Immunotherapies & Transplant Program/Clinic https://www.masseycancercenter.org/cancer-types-and-treatments/cancer-treatments/cellular-immunotherapies-and-transplant-program/	• Stem cell and bone marrow transplantation and cutting-edge clinical trials
VCU Health Radiology Research Services https://radiology.vcu.edu/radiology-research/radiology-research-services/ Radiology Image Resource Center at VCU Health to request images, call 804-828-3543	• Clinical Research protocol setup, as needed, pricing fees, Non-standard reads, duration of study images, etc. • Fulfills research imaging requests • Call to request images and for VCU department-specific setup with Life Image, an electronic cloud base image-sharing network
VCU Health Clinical Pathology Research Services https://pathology.vcu.edu/research/clinical-pathology-cprs/	• Provide laboratory services that support clinical research and Investigators • Fulfills research specimen request • CAP, CLIA, IATA documentation, temperature logs, Lab Supervisor CV, calibration reports, etc. • Clinical Research Pathology Supporting Documents Teams Channel
Tissue and Data Acquisition and Analysis (TDAAC) Services https://www.masseycancercenter.org/research/shared-resource-cores/tissue-and-data-acquisition-and-analysis-core/	• Provide services to clinical research and investigators in high-quality controlled tissue samples
Endoscopy https://www.vcuhealth.org/services/gastroenterology-hepatology-and-nutrition/subspecialties/endoscopy	For testing and scheduling contact • Amanda Jabri Amanda.adair@vcuhealth.org

VCU Health Clinic Scheduling & Testing Centers	
Invasive Cardiology https://intmed.vcu.edu/divisions/cardiology/#department.338842	Contact for testing and scheduling Susan Samer susan.samer@vcuhealth.org
Noninvasive Cardiology, Adults https://www.vcuhealth.org/pauley-heart-center/programs-and-expertise/noninvasive-cardiology	Contacts for testing and scheduling - Virginia McGhee Virginia.McGhee@vcuhealth.org - Shalayia Purcell Shalayia.purcell@vcuhealth.org - Testing and scheduling of ECHO only - James Fredenberger James.fredenberger@vcuhealth.org - Hope Thompson Hope.thompson@vcuhealth.org
Noninvasive Cardiology, Pediatrics https://www.chrichmond.org/services/childrens-hospital-foundation-heart-center/heart-center-specialties/non-invasive-imaging-and-testing	Pediatric Contact for testing and scheduling Cathy Dickens Cathy.dickens@vcuhealth.org
Ophthalmology, Adults https://www.vcuhealth.org/services/ophthalmology/	Contacts for testing and scheduling Shaneika Russell Shaneika.Russell@vcuhealth.org
Ophthalmology, Pediatrics https://eye.vcu.edu/subspecialties/pediatric-ophthalmology/	Contacts for testing and scheduling Lisa McAllister Lisa.mcallister@vcuhealth.org
Adult Clinical Research Unit https://cctr.vcu.edu/support/clinical-research-service-providers/clinical-research-unit/	- Seven bed outpatient / observation unit located on the 8th floor of North Hospital - Specially trained nurses and technicians who are trained to carry out clinical research studies for investigators who conduct clinical research studies
VCU Health Dermatology Research Services https://www.vcuhealth.org/services/dermatology	Contact Andrea Buonomo andrea.buonomo@vcuhealth.org for scheduling and assisting with Clinical Research Services

Clinical Research Regulations, Policies, & Guidance	
Clinical Trials.gov https://clinicaltrials.gov/	Learn about clinical studies from around the world
Code of Federal Regulations (CFR) https://www.ecfr.gov/	Code of Federal Regulations Title 21
U.S. Department of Health and Human Services Office of Human Research Protections https://www.hhs.gov/ohrp/education-and-outreach/about-research-participation/protecting-research-volunteers/principal-regulations/index.html	- Compliance reporting - Regulations and Policies - Education & Outreach - Register IRBs & Obtain FWAs
Guidelines for Good Clinical Practice E6(R3) https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_01_06.pdf	- ICH GCP is the International Council for Harmonisation (ICH) guideline for Good Clinical Practice (GCP) - The guidelines ensures clinical trials are conducted in a way that strictly protects the rights, safety, and well-being of human research subjects