

CRP Quick Guide

Virginia Commonwealth University (VCU) Resources	
<p>Office of the Vice President for Research and Innovation (OVPRI) https://research.vcu.edu/</p> <p>OVPRI, Clinical Research Resources https://research.vcu.edu/human-research/clinical-resources/</p>	<ul style="list-style-type: none"> • 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
<p>VCU Wright Center for Clinical and Translational Research https://ctr.vcu.edu/</p>	<ul style="list-style-type: none"> • Infrastructure and resources that promote interdisciplinary human health research • Collaborations, support, and CRP training and education
<p>VCU Massey Comprehensive Cancer Center (Massey) & Clinical Trials Office (CTO) https://www.masseycancercenter.org/research/clinical-trials-office/</p>	<ul style="list-style-type: none"> • Promote and conduct high-quality cancer-relevant human subject research and facilitate the development of cancer-relevant studies
<p>VCU School of Medicine (SOM) https://medschool.vcu.edu/about/departments/</p>	<ul style="list-style-type: none"> • Includes more than 20 basic health science and clinical / Research departments, affiliate institutes, and centers
<p>Clinical and Translational Science Award (CTSA) https://ctr.vcu.edu/collaborations/ctsa-network/</p>	<ul style="list-style-type: none"> • Collaborations with 60 CTSA to enhance discoveries into treatments for patients, engage communities in clinical research, and train the next generation



VCU Resources	
<p>VCU RAMS Systems https://research.vcu.edu/rams-systems/</p> <ol style="list-style-type: none"> 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. RAMS-IRB - Institutional Review Board 6. RAMS-SPOT - Sponsored Programs Online Tracking 7. RAMS Reports -Access Various RAMS Reports 	<ul style="list-style-type: none"> ● Electronic system for the management of activities provided by the OVPRI ● Guidance and Training ● Explore VCU Research ● Searchable Research Database
<p>VCU & VCU Health: Standard Operating Procedures (SOPs)</p>	<ul style="list-style-type: none"> ● 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 <p>Log in with VCU Health eID and Password:</p> <ul style="list-style-type: none"> ● 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	
<p>VCU File Locker https://ts.vcu.edu/askit/university-resources/vcu-filelocker/</p>	<ul style="list-style-type: none"> • 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
<p>VCU Standard DocuSign https://ts.vcu.edu/askit/university-resources/docusign/</p>	<ul style="list-style-type: none"> • 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
<p>VCU CFR Part 11 Compliant DocuSign https://ts.vcu.edu/askit/university-resources/docusign/fda-part-11-getting-started/</p> <p>Part 11 DocuSign Training https://redcap.vcu.edu/surveys/?s=8KNWMERRPK</p>	<ul style="list-style-type: none"> • 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
<p>VCU Procurement Services https://procurement.vcu.edu/i-want-to/pay-an-individual/compensate-a-research-participant/</p> <p>Prepaid Card Program and Training https://research.vcu.edu/resources/prepaid-card-program/</p>	<ul style="list-style-type: none"> • 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
<p>VCU TriNetX https://apps.cctr.vcu.edu/trinetx</p>	<ul style="list-style-type: none"> • TriNetX is a cohort discovery tool that can be used to conduct feasibility assessments and obtain de-identified data
<p>Collaborative Advance Research Imaging (CARI) https://cctr.vcu.edu/support/clinical-research-service-providers/cari/</p>	<ul style="list-style-type: none"> • Dedicated research facility for a 3.0 Tesla MRI scanner, mock scanner, interview room, drug screening rooms, and more



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<p>Veeva SiteVault https://research.vcu.edu/human-research/regulatory-affairs/veeva/</p> <p>Veeva SiteVault Training Form https://redcap.vcu.edu/surveys/?s=8JP3JDTW8C3RTTPF</p>	<ul style="list-style-type: none"> ● 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
<p>DEEP6 AI Training and Access https://intranet.massey.vcu.edu/clinical-trials-office/training-education-and-development/deep6-resources/</p> <p>DEEP6 Access Request Form https://form.jotform.com/220114850732143</p>	<ul style="list-style-type: none"> ● 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	
<p>VCU Health Intranet: Log in with VCU Health eID and Password https://intranet.vcuhealth.org/sites/clinical-research/</p>	<ul style="list-style-type: none"> ● VCU Clinical Research Intranet ● Research Town Hall Meetings / updates ● Study Team Resources ● Current Studies ● Research Units
<p>Investigational Drug Services (IDS) and Vestigo Services https://research.vcu.edu/human-research/ids/</p> <p>Investigational Drug Services, VCU Health Intranet https://intranet.vcuhealth.org/sites/clinical-research/SitePageModern/79594/investigational-drug-services</p>	<ul style="list-style-type: none"> ● 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
<p>VCUHS Language Services (Access by VCU Health Intranet SharePoint) https://vcuhealth.sharepoint.com/sites/language-services/SitePages/Epic.aspx</p>	<ul style="list-style-type: none"> ● Language Interpreter ● Sign Language ● Combination Text Telephone (TTY) ● Sign Language Cards

VCU Health Clinic Scheduling & Testing Centers	
<p>VCU Health Adult Outpatient Pavilion (AOP) https://www.masseycancercenter.org/aop/</p>	<ul style="list-style-type: none"> • 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
<p>Cellular Immunotherapies & Transplant Program/Clinic https://www.vcuhealth.org/news/vcu-masseys-cellular-immunotherapies-and-transplant-program-expands-with-new-clinic-space</p>	<ul style="list-style-type: none"> • Stem cell and bone marrow transplantation and cutting-edge clinical trials
<p>VCU Health Radiology Research Services https://radiology.vcu.edu/radiology-research/radiology-research-services/</p> <p>Radiology Image Resource Center at VCU Health to request images, call 804-828-3543</p>	<ul style="list-style-type: none"> • 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
<p>VCU Health Clinical Pathology Research Services https://pathology.vcu.edu/research/clinical-pathology-cprs/</p>	<ul style="list-style-type: none"> • 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
<p>Tissue and Data Acquisition and Analysis (TDAAC) Services https://www.masseycancercenter.org/research/shared-resource-cores/tissue-and-data-acquisition-and-analysis-core/</p>	<ul style="list-style-type: none"> • Provide services to clinical research and investigators in high-quality controlled tissue samples
<p>Endoscopy https://www.vcuhealth.org/services/gastroenterology-hepatology-and-nutrition/subspecialties/endoscopy</p>	<p>For testing and scheduling contact</p> <ul style="list-style-type: none"> • Amanda Jabri Amanda.adair@vcuhealth.org

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<p>Invasive Cardiology https://intmed.vcu.edu/divisions/cardiology/#d.en.338842</p>	<p>Contact for testing and scheduling Susan Samer susan.samer@vcuhealth.org</p>
<p>Noninvasive Cardiology, Adults https://www.vcuhealth.org/pauley-heart-center/programs-and-expertise/noninvasive-cardiology</p>	<p>Contacts for testing and scheduling</p> <ul style="list-style-type: none"> ● Virginia McGhee Virginia.McGhee@vcuhealth.org ● Shalaya Purcell Shalaya.purcell@vcuhealth.org <ul style="list-style-type: none"> ○ Testing and scheduling of ECHO only ● James Fredenberger James.fredenberger@vcuhealth.org ● Hope Thompson Hope.thompson@vcuhealth.org
<p>Noninvasive Cardiology, Pediatrics https://www.chrichmond.org/services/childrens-hospital-foundation-heart-center/heart-center-specialties/non-invasive-imaging-and-testing</p>	<p>Pediatric Contact for testing and scheduling</p> <ul style="list-style-type: none"> ● Cathy Dickens Cathy.dickens@vcuhealth.org
<p>Ophthalmology, Adults https://www.vcuhealth.org/services/ophthalmology</p>	<p>Contacts for testing and scheduling</p> <ul style="list-style-type: none"> ● Shaneika Russell Shaneika.Russell@vcuhealth.org
<p>Ophthalmology, Pediatrics https://eye.vcu.edu/subspecialties/pediatric-ophthalmology/</p>	<p>Contacts for testing and scheduling</p> <ul style="list-style-type: none"> ● Lisa McAllister Lisa.mcallister@vcuhealth.org
<p>Adult Clinical Research Unit https://ctr.vcu.edu/support/clinical-research-service-providers/clinical-research-unit/</p>	<ul style="list-style-type: none"> ● 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
<p>VCU Health Dermatology Research Services https://www.vcuhealth.org/services/dermatology</p>	<ul style="list-style-type: none"> ● 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/	<ul style="list-style-type: none"> ● Learn about clinical studies from around the world
Code of Federal Regulations (CFR) https://www.ecfr.gov/	<ul style="list-style-type: none"> ● 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	<ul style="list-style-type: none"> ● Compliance reporting ● Regulations and Policies ● Education & Outreach ● Register IRBs & Obtain FWAs