RESEARCH NEWS

CARILION CLINIC

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THIS EDITION CONTAINS:

MESSAGE FROM OUR LEADERS:

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SPARC (**S**torage and **P**rograms **A**ccelerating **R**esearch **C**ollaborations) is Carilion Clinic's new **secure research environment**, which is an innovative and HIPAA compliant tool for **data storage, access, and use**. This new research tool has the following features to streamline research projects:

Secure *– Data stays protected within Carilion's environment with access only to approved individuals*
Powerful *– Analytic programs for data analysis to occur within the environment*
Accessible *- Cloud environment for secure access from anywhere for ultimate convenience*
Robust*– Scalable storage and processing with versioning and backup processes*
Collaborative *– Leverages institutions' credentials*

How does SPARC work? Once approved to access SPARC, a researcher will log into the SPARC web-based environment using institutional credentials. The SPARC interface allows viewing and accessing project-specific folders. For each project, there are two folders, one for source data and one for research team collaboration. The source data folder is read only; however, a copy of the data may be created in the research team folder for manipulation and edits. The research team can also generate content using *SAS Viya, R, Python, Microsoft Office Suite, AWS products* and save files in this folder. Downloading files from the environment is not allowed unless appropriate permission is obtained. Carilion Health Analytics Research Team (HART) manages the process to transfer files from SPARC to outside the environment. Typical examples include statistical output, manuscripts, presentations, and de-identified datasets. SPARC allows for long-term storage of data in compliance with relevant data retention requirements. Lastly, SPARC can be used for long term storage of data that can be used at a later date.

What projects are currently eligible for SPARC? Initially, SPARC is launching in a reduced capacity. What this means is that current Carilion policy allows SPARC to be used start-to-finish in projects with deidentified data or data sets that would classify as limited and without sensitive data points. Projects that require use of data beyond those categories may use SPARC in research protocols as long as the data imported into SPARC meet the criteria above. Research teams with questions about SPARC eligibility should reach out to Carilion Health Analytics Research Team (HART) (HART@carilionclinic.org) for a study design consultation. Eligibility for limited, sensitive data sets and fully identifiable data sets will be implemented in the future.

Who can request access to SPARC? The Principal Investigator (PI) of a research study has the ultimate responsibility for securely storing, accessing, and analyzing data. The Carilion Clinic PI or their designee should contact Carilion Health Analytics Research Team (HART) to request use of SPARC for their research project or Quality Assurance/Quality Improvement (QA/QI) study. All studies that constitute human research will need to obtain IRB approval for their research protocol. Quality Assurance/Quality Improvement (QA/QI) studies must have formal approval from the department chair or VP (or designee). If the research or Quality Assurance/Quality Improvement (QA/QI) study includes study team members from external institutions the necessary research or data use agreements must be in place prior to approval to use SPARC. At present, VT, UVA and Radford are approved for SPARC access as external collaborators. Independent contractors, working under an agreement directly with Carilion, would be included under Carilion's license. The addition of other external institutions may incur licensing fees, which must be paid by the research project (e.g. grant funding) or by the external institution.

Spotlight on Guideline for Using REDCap for Electronic Informed Consent (eConsent) at Carilion Clinic

Obtaining written consent from research subjects is a critical step in the clinical research process. REDCap offers a digital method to acquire and store subject consent forms through an e-Consent, which provides the ability to obtain consent from subjects remotely or consent subjects in clinic via computer, mobile phone, or tablet. Subjects will have the capability to sign electronically with a stylus, mouse, or finger.

Researchers must describe in the Institutional Review Board (IRB) application how they will obtain consent, and the Institutional Review Board (IRB) must ensure that the consent process is appropriate for the risk level of the proposed research. There are special considerations that must be made for an eConsent process, including verification of subject identity when eConsent will be taking place virtually. The Institutional Review Board (IRB) must approve the use of eConsent, as well as the consent document and consent process for the study, before Carilion Health Analytics Research Team (HART) will build the eConsent in REDCap.

Please note that eConsent may not be utilized at Carilion at this time for Food and Drug Administration (FDA)-regulated research (research involving drugs, devices, or biologics) due to specific Food and Drug Administration (FDA Part 11 regulations that cannot be met by Carilion's current REDCap system.

Guidance regarding the use of eConsent can be reviewed here. Please contact the Institutional Review Board (IRB) at irb@carilionclinic.org if you would like to discuss using eConsent for your research study.

COVID-19 Research

When the COVID-19 pandemic began earlier this year, our Infectious Disease physicians, pharmacists, and clinical trial teams quickly sprang into action to find and implement treatment programs and clinical trials to address the novel coronavirus. Currently, we are participating in several trials, expanded access programs, and surveillance studies to assist in finding new treatment options for patients infected with COVID-19 and to understand the extent of previous exposure. Below is a summary of our clinical research portfolio.

Expanded Access to Convalescent Plasma for the Treatment of Patients with COVID-19
This expanded access program will provide access to investigational convalescent plasma for patients in acute care facilities infected with SARS-CoV-2 who have severe or life-threatening COVID-19, or who are judged by a health care provider to be at high risk of progression to severe or life-threatening disease. This program is led by the FDA and Mayo Clinic with local supervision by Drs. Dorothy Garner and Ekta Bansal.

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Expanded Access Treatment Protocol: Remdesivir (RDV; GS-5734) for the Treatment of SARS-CoV2 (CoV) Infection
Carilion participated in this expanded access program which provided access to investigational Remdesivir for patients who were hospitalized with confirmed SARS-CoV-2 infections requiring mechanical ventilation. This program was sponsored by Gilead Sciences and led by Dr. Garner locally. Shortly after we initiated the expanded access program, the Food and Drug Administration (FDA) issued an Emergency Use Authorization for Remdesivir. This authorization allowed many more healthcare institutions to have access to Remdesivir, which through early trial data showed a benefit in shortening the duration of the virus in participants.

ExtraCorporeal Membrane Oxygenation for 2019 novel Coronavirus Acute Respiratory Disease (ECMOCARD)

This study is a global, Prospective/Retrospective multi-center short period incidence observational study of patients in participating hospitals and intensive care units (ICUs) with 2019 novel coronavirus (COVID-19). This study is led by the International Severe Acute Respiratory and Emerging Infection Consortium globally and Dr. Mark Joseph locally.

OSCAR (Otilimab in Severe COVID-19 Related Disease)

This is a multi-center, double-blind, randomized, placebo-controlled trial to assess the efficacy and safety of Otilimab for the treatment of severe pulmonary COVID-19 related disease. Otilimab is a human monoclonal anti-GM-CSF antibody that has not previously been tested in participants with severe pulmonary COVID-19 related disease. The aim of this study is to evaluate the benefit-risk of a single infusion of Otilimab in the treatment of patients with severe COVID-19 related pulmonary disease. The study population will consist of hospitalized participants with new onset hypoxia requiring significant oxygen support or requiring early invasive mechanical ventilation (less than or equal to [<=] 48 hours before dosing). Participants will be randomized to receive a single intravenous (IV) infusion of Otilimab or placebo, in addition to standard of care. The trial is sponsored by GlaxoSmithKline and is led locally by Dr. Dorothy Garner.

A Multi-site Point Prevalence Study of SARSCoV-2 Seroprevalence Across the Commonwealth of Virginia

This point prevalence survey will measure SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) seroprevalence in individuals presenting to participating outpatient clinics throughout the Commonwealth of Virginia. Outpatient clinics have been selected from each of the Commonwealth's five (5) health planning regions: Central, Eastern, Northern, Southwest and Northwest. Participating institutions include University of Virginia, Carilion Clinic, Virginia Commonwealth University, Sentara, and Inova. Individuals aged 18 or older who reside in the Commonwealth of Virginia and present to the identified outpatient clinics or clinic phlebotomy laboratories for a medical appointment will be approached for recruitment. Eligibility will be stratified to pre-specified quotas of age and race/ethnicity. Up to 5mL of blood will be collected from each subject to test for the presence of SARS-CoV2 antibodies. Secure and Protected Health Information (PHI)-compliant electronic systems will be used to assess eligibility, obtain informed consent, and administer questionnaires. The project is sponsored by the Virginia Department of Health and is led locally by Dr. Francis Farrell and Andrea Bidanset.

TriNetX Quick Facts

228 Users
- 12 training sessions in 2020
- 700 – 1000 queries each month
- https://carilionclinic.org/health-analytics-research-team#self-service-solutions-trinetx-i2b2

109 Clinical Trials received
- 32 clinical trials accepted
- 6.4 day turnaround time

1.22M Carilion patients
- 68M diagnoses
- 71M procedures
- 275M medications
- 232M labs
- 94M vital signs

55M TriNetX Research network patients

60M TriNetX COVID-19 Research network patients

Caisis

Caisis will soon replace CryoTrack as the inventory management system being used within the Carilion Basic Science Research Lab (CBSRL). Caisis is an open source research data management system that was developed at University of Virginia (UVA) but modified for use in the Carilion Basic Science Research Lab (CBSRL) by the Carilion Health Analytics Research Team (HART). The software will be used to support the tracking of specimens for protocol-specific research and biobanking. We will begin piloting Caisis over the next several weeks with an anticipated go-live date scheduled in August. For questions related to Caisis or if you plan to store specimens for research in the Carilion Basic Science Research Lab (CBSRL), please contact Andrew Benson at adbenson@carilionclinic.org or (540) 985-8013.

Research Conflicts of Interest Policy Update

Carilion's Office of Organizational and Integrity (OIC) is pleased to announce several positive changes to the conflicts of interest (COI) process for research. Recently, an updated *Conflicts of Interest in Research* Policy was approved by Carilion leadership that is available now in PageCenterX (PCX) and will also be circulated to department chairs. We are still utilizing the web-based COI-SMART system to solicit COI disclosures; however, some notable changes are listed below:

- Study team members no longer need to create and complete transactional COI questionnaires for each study they join.

- Instead, study team members are expected to complete and maintain accurate, comprehensive disclosures on the COI questionnaire issued by Carilion.
  - COI disclosures only need to be provided/recertified annually OR revised within 30 days of any changes.
  - Please contact Carilion OIC to confirm new team members are in the COI-SMART system.

- Principal Investigators (PIs) will be responsible for certifying that any relevant COI disclosures for the study team are reported to Carilion OIC.
  - New COI language and certification steps are live in PRIS3M for Institutional Review Board (IRB) applications.
  - Research and Development (R&D) will also allow for COI certification prior to application for grant funding.
  - PIs can designate a team member to help; however, the PI is ultimately responsible.

- External collaborators do NOT need to complete the Carilion COI process if their institution possess a Public Health Service (PHS)-compliant Financial Conflict of Interest (FCOI) policy.
  - For those institutions, their institution's IRB should communicate with ours to ensure project compliance.
  - Please contact Carilion OIC if unsure whether a collaborator needs to complete our COI process.

- There will no longer be COI clearance letters issued to study teams unless specifically requested by an IRB, sponsor, or other similar entity.

It is important that COI disclosures are accurate and up to date for timely review. This means ensuring that the Key Research Personnel question (#20 or 21) has been completed properly by indicating all types of funding (including estimated value) or roles for all current research projects. Individuals also need to disclose all paid travel (including estimated value) and paid meals (including estimated value) as well as any consulting or provision of medical education and other services (including estimated value). Please go to https://carilionclinic.coi-smart.com via Mozilla Firefox or Google Chrome and log in using your Carilion credentials to review and revise your previous disclosures.

Additionally, a new Policy was approved that establishes a Carilion Clinic Research COI Committee (RCOIC) to help review potential incidents of COI in research, and when necessary, to develop appropriate management plans. The Carilion Clinic RCOIC will consist of members from several research-related administrative departments as well as physician researcher stakeholders. *Ad hoc* members will also contribute as needed depending on the needs of the project and nature of the conflict.

Due to these significant changes, those participating in research at Carilion will need to complete new institutional COI training as per federal regulations. That training will be available in Carilion's Collaborative Institutional Training Initiative (CITI Program) course dashboard by the end of July and should be completed as soon as possible.

For any questions about these changes or if you are interested in participating in the Carilion Clinic Research COI Committee (RCOIC), please feel free to contact Carilion's Office of Organizational and Integrity (OIC) at researchcompliance@carilionclinic.org or Dr. Allison McKell directly at aomckell@carilionclinc.org. Thank you to everyone who contributed to this update!

Human Research Protections Office/IRB Feedback Survey

In the spirit of continuous quality improvement, the Human Research Protections Office (HRPO) seeks ongoing feedback from the research community we serve. In that regard, the HRPO is requesting researchers complete a feedback survey at the time they receive their Institutional Review Board (IRB) outcome letter for a specific submission. The survey is designed to solicit feedback based on that specific submission, and the link to the survey will be provided in the email researchers receive when the submission has been processed by the IRB. The member of the study team who worked the most closely with IRB should complete the survey, and please complete only once for each submission. Responses are anonymous unless you provide contact information. The survey is expected to take less than 5 minutes. Responses from submitted surveys will be reviewed on a quarterly basis by the HRPO Director and areas of focused improvement will be based on the responses.

New Employees and Transfers

WETLAB Operations:

Daniella Rodriguez, Clinical Research Assistant – supporting Beam Diagnostics

Daniella Rodriguez is the new Clinical Research Assistant supporting research being conducted by BEAM Diagnostics. Daniella brings several years of research and clinical experience with her to Carilion. Under a Howard Hughes Medical Institute EXROP fellowship, Daniella studied the Hippo signaling pathway which is responsible for controlling organ size in mammals. Prior to working at Carilion, Daniella worked as an emergency medical technician for two years in Albuquerque, NM.

Andrea Yu-Shan Chevez, Clinical Research Assistant – supporting the Orthopaedic Hand Clinic

Andrea Yu-Shan Chevez is the new Clinical Research Assistant that will be supporting Dr. Peter Apel's research in the Orthopaedic Hand Clinic. Andrea is a recent graduate of Virginia Tech where she received her BS in psychology. Under the guidance of Dr. Julie Dunsmore, Andrea spent two years studying how children develop relationships as they mature. Additionally, she was named a Translational Obesity Undergraduate Research (TOUR) Summer Scholar, which allowed her to complete a summer rotation in the Physical Activity Research & Community Implementation lab at Virginia Tech.

Research & Development:

Cara Spivey, Clinical Research Coordinator I – VTCSOM

Cara Spivey is a local educator who brings her years of experience to the School of Medicine working with our Medical Students on their various research endeavors. Her attention to detail, energy and compassion make her a wonderful addition to our research team.

Dustin Rasnick, Clinical Research Coordinator II – Radiology

Dustin Rasnick is the new Clinical Research Coordinator for the Department of Radiology. He is a former Radiology Technician and previously worked with Carilion in TSG for several years before joining us in Research. His technical expertise and analytical skills are a welcome addition to our team.

Bryce Lewis, Clinical Research Coordinator II – Psychiatry

Bryce Lewis is the new Clinical Research Coordinator for the Department of Psychiatry. Bryce is a graduate of Radford University receiving his MS in Clinical-Counseling Psychology. Before joining Carilion, he worked as a Mental Health Counselor for 5 years at New River Valley Community Services, then with a marketing firm for the last few years. His unique experience will be a value-add to our research efforts in Psychiatry as we pursue more research opportunities and expand our research footprint.

Shakeel Ahmed, Clinical Research Coordinator III – Research & Development

Shakeel Ahmed joins us from Chicago, IL. Having previously worked in hospital sites across the country and for a major Biotech company we welcome his industry experience and drive to our R&D Coordinator team.

Resource Links: Click on keyword below

Research and Development Human Research Protections Office
CITI
Health Analytics Research Team
TriNetX
iTHRIV
PRIS3M Online IRB Submission System