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RESEARCHER SPOTLIGHT

Jason Foerst, MD, Medical Director of the Carilion Clinic Structural Heart and Valve Center, is involved in multiple early feasibility and pivotal device trials. Recently, he was recognized for enrolling the first participant nationwide in the CORCINCH-HF study, a Randomized Clinical Evaluation of the AccuCinch® Ventricular Restoration System in Patients who Present with Symptomatic Heart Failure with Reduced Ejection Fraction (HFrEF). This accomplishment garnered attention at the national and local level, shining light on the cutting-edge clinical research conducted in structural cardiology. He and his clinical research nurse, Vivian Wilson, as well as all of the staff in structural cardiology work tirelessly to offer multiple clinical trials to patients in need. The goal of the study is to explore AccuCinch® Ventricular Repair System as a potential treatment option for heart failure patients who have symptoms such as shortness of breath, fatigue and swelling because the left ventricle of the heart is not functioning properly. Currently, there are no other treatments available for this complex heart failure condition. Carilion's Cardiovascular Institute is one of the few select sites to participate nationwide.



Jason Foerst, MD
Structural Cardiology

NEED HELP NAGIVATING RESEARCH OR QA/QI PROCESSES AT CARILION?

Visit MyProjectPath for guidance at <https://redcap.link/MyProjectPath>

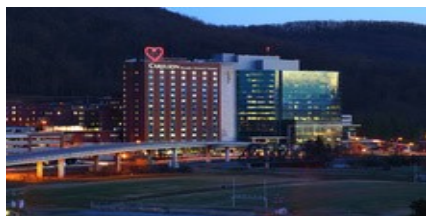
**See [page 9](#) for more details

ADDICTION RESEARCH COMMUNITY OF ROANOKE VALLEY

The Addiction Research Community of Roanoke Valley (ARC-RV) is comprised of an active, dedicated group of individuals who are committed to increasing research activities on addictions in our region. The group has a shared interest in raising awareness of current research in five areas of addiction including:

- Alcohol
- Tobacco
- Opioids
- Methamphetamines
- Food

The group meets the first Wednesday of each month from 5:30 – 6:30 pm. Meetings will continue to be conducted virtually for the next several months due to COVID-19 and will break for July and August. Meetings consist of an invited presenter summarizing his/her addiction-related research project followed by open discussion among participants. Participation is open to anyone interested in learning about the groundbreaking research going on right here in our area! If you are interested in learning more, please contact Deirdre Rea, ARC-RV Director at DORea@carilionclinic.org.



SEROPREVALENCE STUDY UPDATE

A point prevalence study was conducted during November/ December 2020 in Southwest Virginia to ascertain the seroprevalence of COVID-19 antibodies in the general population. The study was complementary to the recently completed Commonwealth Seroprevalence Study conducted across the entire state of Virginia. The Commonwealth study was limited to participants with a pre-existing laboratory order. On the other hand, this study utilized email, direct mailing and social media to sample the general population spread across 25 municipalities in Southwest Virginia. Sampling was stratified by race/ ethnicity to match the demographic profiles of each municipality. 4217 participants had their blood evaluated for the presence of COVID-19 antibodies. Of these, 262 participants were positive, yielding an unadjusted overall seroprevalence of 6.2 % (95 % CI 5.5 %-7.0 %). Positivity by county ranged from 18.2 % (95 % CI 4.0 %- 48.9 %) in Russell to 0.0 % (95% CI 0.0 %- 32.1 %) in Smyth. Franklin County had the highest number of seropositive participants, 34/417 (8.15 %), followed by the city of Salem 27/278. The highest number of positive participants by age group was observed in the 55-60 age group 38/442, an unadjusted seroprevalence of 8.6 % (95 % CI 6.2 %- 11.7 %). Lastly, unadjusted seropositivity was greater in females, 7.34 % (189/2576) as compared to males, 4.93 % (70/1421). In summary, this study demonstrated that the seroprevalence in Southwest Virginia increased six-fold within four months. Additionally, the study demonstrated a seroprevalence study could also be effectively conducted with a team science approach utilizing social media as a mechanism to disseminate information. A final report is currently being drafted for dissemination.

RESEARCH DAY 2021

The 13th Annual Research Day was held on April 13th, 2021. Although the event was converted to a virtual format, participation was extremely high with over 104 abstracts submitted from Resident/ Fellows, Faculty/ Staff and Students. Of the 104 abstracts submitted, 27 abstracts were accepted for oral presentations. Utilizing WebEx, the presenters gave their talks in real time from over 14 locations. Participation was broad across clinical departments including Dentistry, Dermatology, Medicine, Family and Community Medicine, Nursing, Obstetrics/ Gynecology, Pediatrics, Pharmacy, Psychiatry and Surgery. The keynote speaker was Andre Muelenaer, MD retired section chief of Pediatric Pulmonology and Professor of Practice, Biomedical Engineering and Mechanics, Virginia Tech. Dr. Muelenaer gave an excellent overview of the emergence of Carilion Clinic from a regional hospital. He also highlighted the synergistic collaborations between Carilion Clinic and Virginia Tech on the Blacksburg and Roanoke Campuses. The overall theme of the meeting was that research and innovation was vibrant during 2020-2021 even though personnel were extremely busy coping with the COVID-19 pandemic. The abstract, program and posters will be made available at <https://www.carilionclinic.org/research>.

Periodically, we will invite a researcher to describe their experience with SPARC, Storage and Programs Accelerating Research Collaborations. The first entry is by Ian Crandell, PhD, Center for Biostatistics and Health Data Science, Virginia Tech

It's no exaggeration to say that the onset of the COVID-19 pandemic upended almost every aspect of our lives. As governments struggled with difficult policy choices and individuals adapted to new ways of living and working, the statistical and medical communities worked frantically to find the best solutions to COVID-19 as quickly as possible. Because of the scope and urgency of the problem, research findings came out rapidly, and much of the work suffered from a lack of rigor. As biostatisticians, at Virginia Tech's Center for Biostatistics and Health Data Sciences (CBHDS), we realized that it was in this area that we could do the most good.

We knew that in order to succeed we needed to assemble a diverse team with a wide base of expertise. We would need to work with clinicians to provide the scientific and medical expertise to identify relevant clinical outcomes and variables. We would need access to a large database of medical records to study, as well as collaborators knowledgeable in the use of such systems. Finally, we needed access to a computational environment with the power to analyze large data sets as well as protocols to ensure data privacy and security. With those elements in place, we could begin to study COVID-19 outcomes with the tools and rigor appropriate for large observational data sets.

Our collaboration began with ongoing conversations between Alex Hanlon, PhD, Director of CBHDS, and Phyllis Whitehead, PhD, APRN, ACPNP, PMGT-BC, FNAP, a palliative medicine advanced practice nurse, researcher, and clinical ethicist at Carilion Clinic. They identified unclear results in the medical literature studying the relationship between COVID-19 outcomes and vitamin D and hypothesized that those results may be attributed to confounders not adjusted for, a moderating effect of race on that relationship, or likely both. To study this, Drs. Hanlon and Whitehead reached out to Kim Carter, PhD, RN, NEA-BC, Senior Director of Nursing Research, EBP & Excellence at Carilion Clinic. Drs. Carter and Whitehead provided the knowledge about COVID-19, clinical outcomes, and clinical practice needed to ensure we were asking the right questions, as well as support for making connections with appropriate Carilion services, navigating human subjects protections, and copy editing. Our team was further strengthened by partnering with Michelle Rockwell, PhD, a Registered Dietitian and health services researcher with Carilion Clinic Family & Community Medicine and the Fralin Life Sciences Institute at Virginia Tech. Dr. Rockwell's deep understanding of vitamin D and its biological effects allowed us to target the appropriate molecule to study as well as to put our results in context with the broader nutrition literature. With the biological and clinical expertise of our collaborators, Dr. Hanlon and I were in position to collaborate with the team through the phases of research and publication and to use our skills in rigorous observational data analysis to begin addressing our research questions.

An analysis is only as good as the data that go into it. When we began formulating our query in June of 2020, COVID-19 was still relatively uncommon in the United States, and to get the amount of data we would need required access to medical records from across the country. This need was the impetus for our collaboration with Mattie Tenzer, Director of the Health Analytics Research Team (HART) at Carilion Clinic. Carilion Clinic is a partner in the TriNetX COVID-19 research network, an electronic health records (EHR) database with data for over 30 million patients at the time of our study. Working with Ms. Tenzer, we were trained to use TriNetX's online data browsing tool and began formulating our

query. For our study, we needed to find patients with a COVID-19 test on record, as well as a vitamin D test at most 90 days before the COVID-19 test. COVID-19 was not yet as well-coded in EHRs as it is today and determining which terms to include in our database search was a non-trivial task. Fortunately, we had ample expertise in medicine and medical coding from Ms. Tenzer, along with Drs. Carter and Whitehead, to guide us. With Dr. Rockwell's help focusing our search to the right codes for vitamin D, we were able to construct the query and download the data into Carilion's SPARC computing environment.

Our team was one of the first to use Carilion Clinic's SPARC environment, and the first to produce and submit a manuscript from start to finish using TriNetX data housed within it. Because the system was so new, there were still some wrinkles to be ironed out. These problems were solved through an iterative collaborative process between me and Daniel Graft, a Carilion Clinic system engineer. Since our team was the first at Carilion to work with such a large dataset within SPARC, we were able to stress test the computational limits of the system and identify points for improvement in the software interface. Mr. Graft and I were able to greatly improve the user experience in the SPARC environment by expanding the available memory and fine-tuning SPARC's Amazon Web Services interface. While the process was difficult at times, the end result was a more powerful, more usable, and much friendlier environment for subsequent EHR data research.

With our team assembled and our computational environment in good order, we began the analysis of vitamin D status and COVID-19 outcomes. The biology behind both COVID-19 and vitamin D is complicated, and the relationship is influenced by many confounding factors. We knew that accounting for these confounders in our data analysis would be a daunting task. Fortunately, because Carilion's SPARC environment allowed us to work with very large data sets, our problem was amenable to data re-balancing methodologies, particularly matching and weighting based on propensity scores. Using these techniques, we produced estimates for the effect of vitamin D on COVID-19 test positivity, which were robust to confounding due to age, sex, ethnicity, and comorbidities which comprise the Charlson comorbidity index.

Working almost entirely within Carilion's SPARC environment, our team successfully completed and submitted a manuscript entitled "Examination of the Moderating Effect of Race on the Relationship between Vitamin D Status and COVID-19 Test Positivity using Propensity Score Methods," to a leading nutrition science journal, where it is currently undergoing peer review. The second phase of our project has now grown to include an educational component, and I am guiding VT Computational Modeling and Data Analytics undergraduate Mitchell Neat through data analysis in SPARC.

When I reflect on working in SPARC, I think not only of the hours I've spent coding in the environment, but also about what it means to be in there and all the steps it took to get there. But the computing environment isn't a destination, it is a platform where you can map out the most direct paths from your questions to their answers. It's a critical piece of the big data puzzle, but not the only one. Working in SPARC means working alongside clinicians, biological scientists, informaticians, data analysts, engineers and students. I consider myself extremely fortunate that this partnership has led to achievements in science, engineering, and collaboration. As large EHR data sets become more common and accessible to researchers, collaborations of this size and scope will only become more prevalent. The level of statistical, medical, computational, and engineering knowledge needed to tackle these kinds of problems is too great for any one person. Big data requires team science, and I'm honored to be a part of it at Carilion.

Ian Crandell, Ph.D., Virginia Tech CBAHDS

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POLICY & SOP UPDATES

Every three years, Research and Development reviews and revises our catalog of Standard Operating Procedures (SOPs) and our system-wide policies. Our SOP catalog has six sections pertaining to general administration, study start-up, project management, subject management, data management, and quality assurance. The SOPs offer practical guidelines for clinical trial management at Carilion Clinic. Thus far, sections 100-200 have been updated for 2021 and are posted to the [R&D intranet page](#). Revisions to the 300-600 sections will be available in the coming months. Anyone involved in clinical research at Carilion Clinic is encouraged to review and implement our SOPs.

R&D also oversees system-wide policies that govern research at Carilion Clinic. These are available for review on PageCenterX and cover topics regarding research administration and finance, effort reporting, PI eligibility, research fee schedules and indirect rates, as well as research billing compliance. Among our recently revised policies includes the Reimbursement and Compensation to Study Participants policy. Key takeaways include the following:

- W-9 forms are not required for studies that dispense less than \$100.00 per calendar year
- If a study dispenses more than \$100 per calendar year, a signed W-9 form must be collected and submitted to accounts payable for tax purposes
- Participant stipends in excess of \$600 per calendar year are considered taxable income
- Accounts payable will issue 1099 forms to any participants exceeding the \$600 threshold

Please refer to the Reimbursement and Compensation to Study Participants Policy on PageCenterX for further details or contact R&D.

EPIC RESEARCH UPDATES – RESEARCH BILLING

The headline that NO ONE wants to see - “Hospital Fined \$5,000,000 by Centers for Medicare and Medicaid Services for Improper Clinical Trial Billing”

While this is not a real headline, many Academic Medical Centers and healthcare organizations across the country have been the subject of such unflattering media coverage. To prevent clinical research billing non-compliance, Carilion has built a system within Epic to identify, link, and route research charges quickly and accurately. Below is a summary of the types of research projects in Epic and a glimpse of the workflow in action.

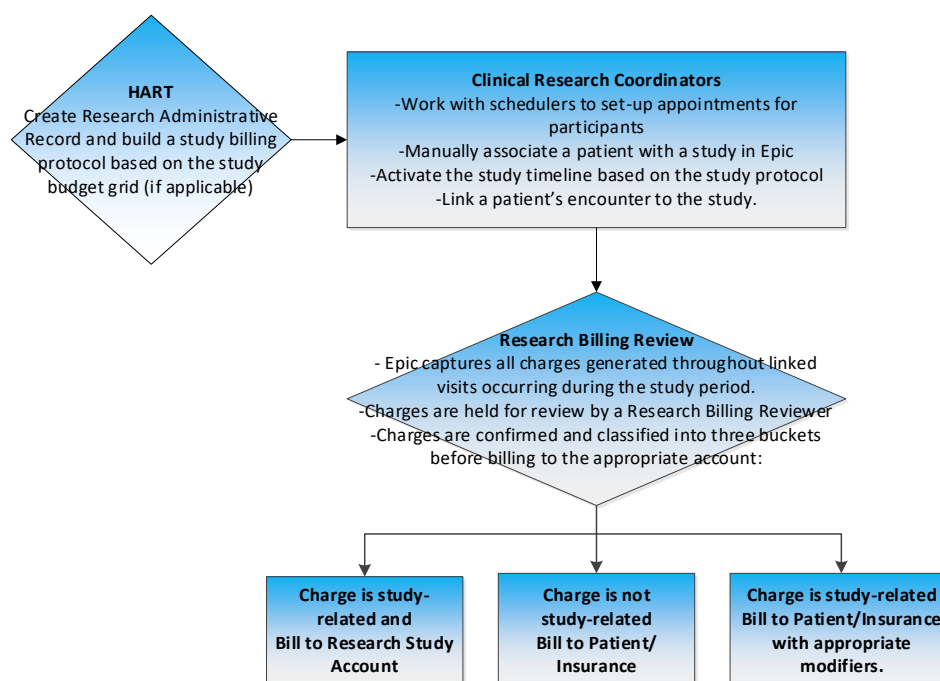
Types of Research Projects in Epic:

- Research registry
 - No research charges
 - Data collection only
- Standard of care study
 - No research charges

- All procedures align with routine care
- Sponsored clinical trials
 - Typically includes research charges
 - Many protocol-driven procedures that often are outside of the scope of routine care
- Investigator-initiated clinical trials
 - Possible research charges
 - May not involve a study drug or device, but may include protocol-driven procedures that are outside of the scope of routine care

Each research project is set up to track patients who are enrolled in a research study and allows for linking of associated research charges. The research administrative record in Epic includes fields such as the study name, NCT number, IRB number, a brief study description visible to Epic users, the principal investigator, and research coordinators.

A chart summarizing Epic's research billing workflow:



Conclusion:

As our portfolio of clinical research has increased, so have the demands for research billing compliance. These streamlined workflows in Epic provide transparent documentation, enable efficient routing and payment of research charges, and significantly reduce risk of research billing errors. Altogether, it represents an effective and scalable system to support clinical research at Carilion Clinic.

APRIL 20TH OCPD SESSION

The April 20th Office of Continuing Professional Development (OCPD) session will provide an overview of investigator-initiated multi-site research studies. If you've ever considered planning a research project that involves collaborating sites, this session will provide useful information on how to structure the project for success. Topics will include how to define and formulate key operational objectives, best practices for team collaborations, and understanding the review criteria used by funders.

The session will be presented by Vera Hollen, MA, Grants Management Administrator in the Research & Development Office. For assistance with investigator-initiated projects and grant funding, please contact Vera Hollen at VLHollen@carilionclinic.org.

NEW EMPLOYEES

Andrea Yu-Shan, BS, Clinical Research Coordinator I – Orthopaedics

Andrea Yu-Shan is a new Clinical Research Coordinator who will be supporting research in the Orthopaedics Department. Andrea graduated from Virginia Tech with a B.S. in Psychology. During her time there she worked as an undergraduate research assistant in the Social Development Lab and the Physical Activity Research & Community Implementation Lab. Most recently, Andrea has worked as a Research Assistant supporting Dr. Apel in Orthopaedics, while also working as a scribe.

Daniella Rodriguez, BS, Clinical Research Coordinator II – Emergency Medicine

Daniella Rodriguez is a new Clinical Research Coordinator who will be supporting research in the Emergency Medicine Department. Daniella graduated from Juniata College with B.S. degrees in Biochemistry and Spanish & Hispanic Cultures. She has prior experience working as an EMT and most recently has been working as a Research Assistant primarily supporting Dr. Kablinger's BEAM Opioid study.

Lucas Arney, BS, Clinical Research Assistant – Emergency Medicine

Lucas Arney is a new Clinical Research Assistant who will be supporting Dr. Damon Kuehl's HeadSMART II trial. Lucas graduated from William and Mary with BS degrees in neurosurgery and kinesiology. Lucas has several years of undergraduate research experience and most recently worked as a medical scribe in the Carilion Emergency Department.

William Loftus, MA, Clinical Research Assistant – Emergency Medicine

William Loftus is a new Clinical Research Assistant who will be supporting Dr. Damon Kuehl's HeadSMART II trial. William graduated with a BA in psychology from the University of Chicago and a MA in psychology from UCLA. William has several years of graduate and undergraduate research experience. Prior to coming to Carilion, William worked as a grant consultant at Thomas P. Loftus Consulting.

Darren Hackley, MA, Clinical Research Assistant/Scribe – Orthopaedics (Hand Clinic)

Darren Hackley is a new Clinical Research Assistant and Medical Scribe who will be supporting Dr. Peter Apel's grant-funded research projects and working as a medical scribe for Dr. Cesar Bravo. Darren holds BS degrees in biomedical sciences and psychology, as well as a MA in molecular medicine from Liberty University. Darren is a licensed CNA and has amassed thousands of clinical hours working in that capacity and as a medical scribe. Darren most recently worked as a scribe for Carilion Orthopaedic Surgery.

RESOURCE LINKS

[Research and Development](#)

[Human Research Protections Office](#)

[CITI](#)

[Health Analytics Research Team](#)

[TriNetX](#)

[iTHRIV](#)

[PRIS3M Online IRB Submission System](#)

COI-SMART



IMPORTANT NOTE

Carilion Clinic's annual Conflicts of Interest (COI) disclosure cycle was moved from October 2020 to April 2021. Anyone receiving emails from COI-SMART should complete or verify their disclosures. Key research personnel should ensure they answer "Yes" to question 20. New general COI education is available in Cornerstone and an updated research COI module will be available there soon. Organizational Integrity and Compliance apologizes for any confusion associated with this launch. For any questions or technical issues, please reach out to Allison McKell at aomckell@carilionclinic.org or (540) 529-6774.



iTHRIV UPDATES:

Upcoming Workshops and general information: <https://portal.ithriv.org/#/home>

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RESEARCH/QA/QI PROCESS

This new tool will provide as much or as little information and support as you want, based on questions you answer. In addition, you can track your progress, associated costs, and receive a PDF summary.

This figure presents an overview of the process, and we invite you to visit [MyProjectPath](#) for more in depth information tailored for your specific project. Please contact HART@carilionclinic.org with questions.

