RESEARCH NEWS

CARILION CLINIC

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THIS EDITION CONTAINS:

MESSAGE FROM OUR LEADERS:

Colleagues,

Firstly, I want to applaud everyone for your tireless efforts and dedication as we cope with the COVID-19 pandemic in our community. Although many of you are actively engaged in the clinical care of our patients, some of you will also be contributing to the resolution of the pandemic through future research endeavors. Carilion Clinic is poised to contribute to this effort through the evaluation of novel therapeutics in clinical research trials, investigator-initiated studies to explore a hypothesis, and data sharing with research collaborators worldwide. Over the last five years, Carilion Clinic has doubled the number of studies with research ongoing in every clinical department. Coupled with this expansion is the adoption of online applications for research approval and IRB submissions to streamline processes previously performed on paper with routing to secure signature approvals. For this reason, although many research studies are paused due to COVID-19, the review and approval of studies is ongoing albeit remotely. Moreover, working in parallel with other departments remotely, we were able to successfully submit a large federal grant under an accelerated timeline.

In closing, Carilion Clinic Research Operations will not be immune to the organizational ramifications of COVID-19. That said, it is important to maintain your curiosity to explore healthcare solutions through research. If you have an idea, please discuss with your department chair and utilize our online application https://is.gd/RnD_eCRAF**.** In most cases, we can provide feedback and approval within days of your submission.

Regards and stay safe!

Daniel P. Harrington, MD
Vice President of Academic Affairs

Research and the COVID-19 Pandemic

In the context of rapidly evolving circumstances regarding COVID-19, and the Organization's focus on social distancing and the health and well-being of the community, effective immediately, **all in-person non-essential research study activities, including recruitment and enrollment,** are to be **PAUSED** until further notice.

The following guidance is given for the definition of essential and non-essential studies:

Essential Studies are any studies utilizing drugs, biologics or devices that hold the prospect of direct benefit to the patient, or studies in which canceling or postponing the activities would increase the risk to the subject's safety or wellbeing. Furthermore, any study involving therapeutic radiation would be considered essential. All principal investigators must assess their studies to identify those they believe must continue with in-person study activities due to the health and well-being of the participant. All other studies and study activities are to be considered non-essential.

Non-essential Studies are observational or behavioral studies, focus groups, retrospective studies, data/sample-based research studies. In addition, non-critical interventional studies that may pose a risk to Carilion Clinic research staff and Carilion Clinic employees are included as non-essential.

Research activities that involve no face-to-face interactions with subjects may continue.

All investigators working remotely on data that potentially contain patient information must be aware that such data may not be downloaded on non-Carilion computers. You should remotely log in to the appropriate server using the VPN. Since VPNs can become overloaded, please log out when you do not require secure access.

We appreciate your adherence to this directive. If you have any questions, please contact the following individuals for:

Institutional Review Board and Human Research Protections:

Carley Emerson caemerson@carilionclinic.org or 540-769-7888

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Research and Development: Francis Farrell fxfarrell@carilionclinic.org or 540-589-8555 research@carilionclinic.org

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Health Analytics: Mattie Tenzer mmtenzer@carilionclinic.org or 540-529-4654

Office of Organizational Integrity and Compliance: Allison McKell aomckell@carilionclinic.org or 540-510-4645

Reminders:

A reminder that R&D is requiring training modules for **funded** studies, replacing the previous Cornerstone education modules. They are required for all NEW studies starting March 1st, 2020.

Grant Funded Studies: Grant Proposal Development Module

All Funded Studies (Grant and Industry): Essentials of Research Administration Module

Modules can be accessed via Citiprogram.org

FREQUENTLY ASKED QUESTIONS

What is the effect of the PAUSE on pending studies or studies we wish to submit to the IRB in the near future?
The IRB will continue to review and approve submissions. For studies that are approvable but involve in-person interactions with study subjects and do not have the potential for direct benefit, the IRB will approve the study but explicitly note that enrollment may not start until the pause in activities is lifted.

How do subjects need to be notified of visit cancellations and changes?
When a study visit needs to be cancelled or changed to a phone call or online encounter, the subject should be told the reason and that they will be contacted again when the visit can be rescheduled. These messages to subjects do not require IRB approval but should be documented in your research record.

If it is possible to conduct my study remotely, but the consent process is IRB approved as being obtained through an in-person visit with a signed consent, can I instead obtain consent over the phone?

Any proposed change to the way consent is being obtained must be submitted to the IRB as an amendment.

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The IRB will be flexible during this time, but the research study will still have to meet certain regulatory criteria for a waiver of signed consent to be granted. Investigators should be sure to describe in the amendment how they will provide the consent document to the participant ahead of time, how they will ensure the participant's understanding of the research, and how they will document the verbal consent in the research record.

How does the IRB need to be notified of visit changes?

Study visit changes must be made in a way that protects the safety and well-being of subjects, and therefore such changes, including the conduct of a study visit virtually (by remote means) or outside of window, omitting a specific research procedure, collecting questionnaire/assessment data over the phone instead of in person, and/or missed research visits would be considered minor deviations. Minor protocol deviations should be documented within the research record and must be reported to the IRB at time of Continuing Review through submission of a Deviation Log.

These changes do NOT require prior IRB approval. If a circumstance does arise with the potential to harm a subject (for example, a crucial in-person treatment or safety visit is impossible), the study team's focus should be on ways to mitigate the potential harm. After this occurs, the IRB should be notified by a Promptly Reportable Events submission.

Can students actively work on research studies under a PIs direction at this time?

Students cannot have direct in-person contact with research participants at this time. They should limit their involvement to remote activities.

I have already scheduled an in-person visit with my study participant, should I cancel the visit?

Yes, all future in-person non-essential research visits should be cancelled immediately until further notice.

Can I consent/enroll a patient into a clinical trial for a study that has a direct and potential life-saving benefit such as a heart valve?

Yes, this would be considered an essential trial and may proceed.

My study is paused, but the IRB approval is expiring/due for check in soon. Should I still complete and submit the Continuing Review submission to the IRB?

Yes. If you will wish to resume the study after the pause, then the study should remain IRB approved so that when the pause is lifted, you may immediately resume the study. If you do not wish to resume the study, then please submit a closure report.

The IRB will be flexible in this uncertain time, especially in regard to research enrollment and research progress, as we understand clinical care is the primary focus and research is secondary. That being said, if the research study expires, all research activities may not begin again until the pause is lifted, **and** the study is reapproved by the IRB.

Are the Departments of Research, Institutional Review Board, Health Analytics, and Office of Integrity and Compliance still operating under normal procedures?

Yes, all programs are fully functional and operating at our standard capacity, albeit remotely.

Who else needs to be notified of the pause?

The PI of studies with another IRB of record (studies relying on another IRB, such as WIRB or NCI) should contact that IRB to let them know about the PAUSE and determine any additional reporting requirements.

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Updates to R&D Application in REDCap

Research and Development strives to continuously improve its processes for managing clinical research at Carilion Clinic. As a highly regulated field, clinical research is subject to oversight from many regulatory bodies, including Centers for Medicare and Medicaid Services (CMS). CMS has issued policies that inform clinical research billing practices for drugs, biologics, diagnostic interventions, and devices. These are known as the Clinical Trial Policy (NCD 310.1) and the Medicare Benefit Policy Manual - Chapter 14, IDE Devices, which outline specific criteria for billing CMS in the context of a clinical trial.

R&D has always played a role in clinical research billing compliance at Carilion Clinic but will now offer enhanced documentation via a new workflow built into our R&D application for new research. This workflow will populate when an Investigator or study team member selects "Clinical Trial" as the type of research. Then, based on the selection of "Drug, Biologic, Diagnostic Intervention" or "Device", a series of questions will populate that will guide the investigator through the required CMS billing criteria.

The answers submitted by the Investigator and/or study team members will generate a real-time determination of the trial's CMS qualifying status. This determination provides documentation in the event of an audit and improves the process for budgeting and clinical research billing compliance.

A study that meets the CMS qualifying criteria may bill the following to CMS:

- Items or services that are typically provided absent a clinical trial (e.g., "conventional care");
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, in particular, for the diagnosis or treatment of complications.

Items that cannot be billed to CMS include:

- The investigational item or service itself, unless otherwise covered outside of the clinical trial;
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
- Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

R&D then reviews the CMS qualifying status generated from the R&D application to assist study teams with their study budgets and coverage analyses. Further, it is entered into an Epic Research Study Build to automate research participants' charges to the appropriate account. These actions together ensure that we are compliant in our research billing practices.

Special thanks to Min Wang, PhD, from HART for her exceptional work in preparing the REDCap workflow.

Spotlight on Peter Apel, MD, PhD

Dr. Peter Apel, MD, PhD, Orthopedic Surgeon with Carilion Clinic and Assistant Professor at the Virginia Tech Carilion School of Medicine, received a two-year research grant award from the Orthopedic Research and Education Foundation. The project entitled, "When can patients safely drive after rotator cuff repair?" will test driving fitness of post-operative patients using a unique on-road, in-sling multidimensional approach.

Despite over 450,000 annual arthroscopic rotator cuff repairs (RTCR)s in the US alone, surprisingly little data exists for guiding return-to-drive recommendations. Surgeon-imposed restrictions on return to driving create significant hardships for patients and may not be necessary. Postoperative restrictions are burdensome to patients both financially and socially. Typical driving restrictions are in the range of 6-8 weeks. This creates a significant hurdle for patients to get to therapy, attend appointments, get to work, and is associated with increased financial and societal burden.

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Data previously collected data by Dr. Apel and his team has shown that subjects drive more conservatively when they perceive that they are physically impaired. Furthermore, they hypothesize that patients with rotator cuff tears have developed adaptive driving behaviors due to the chronicity of the rotator cuff tear. Therefore, they hypothesize that the sling restrictions will have minimal impact on driving fitness in actual RTCR patients and may actually have no impact due to pre-surgical adaptive behaviors. Patients have a strong desire to return to driving as they need to get to therapy, to work and to other locations for daily activities. Thus, there is a clear need for realistic evaluation of patient driving fitness after RTCR.

The study will recruit 32 adults between the ages of 40 and 69 to participate. Approximately 2 weeks prior to their scheduled RTCR, subjects will be evaluated to measure their preoperative (baseline) driving fitness. The subjects will be accompanied by a trained researcher from VTTI to an instrumented vehicle, where data collection will occur. This vehicle includes rear-seat controls (steering wheel and brake pedal) that allow the researcher to assume partial control of the vehicle if necessary. The subjects will complete an approximately 60-minute driving fitness evaluation comprised of a series of tasks including driving on surface streets and controlled access highways, driving on rural roads and city streets, making left and right turns, driving in reverse, parallel parking, reverse parking, and perpendicular parking. All driving tests will be completed with an experienced driving researcher accompanying the subjects for the entirety of the evaluation.

At 2- and 4-weeks post-surgery, subjects will perform the driving test in their required sling. At 6 weeks following surgery, it is anticipated that patients will be medically cleared to come out of the sling during their standard of care post-operative evaluation. Following this clinic visit, the subjects will perform the 6-week experimental drive. Data will be analyzed to test the hypothesis that driving fitness of patients who have undergone RTCR will not be impaired postoperatively.

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This study will develop standardized return to driving recommendations based on the subject's driving assessments. If researchers find that subjects can safely drive 2 weeks postoperatively, the research will permit surgeons to confidently recommend an earlier return to driving. If 6 to 8 weeks is found to be the appropriate time to return to driving, the standardized recommendation will eliminate the confusion and guesswork that currently surrounds the return to driving decision for nearly half a million patients per year.

New Employees and Transfers

Tanner Harmon joined the staff of the IRB in March 2020. He graduated with a B.S. in Human Nutrition, Foods, and Exercise Science and Chemistry from Virginia Tech, as well as most recently obtaining his M.H.A. from Jefferson College of Health Sciences.

After graduating in 2019 from Jefferson, he began his career with Carilion as the Ambulatory Scribe Manager in the Emergency Medicine Department and has recently transferred to The Human Research Protections Office as an Operations Consultant.

Outside of work, he enjoys traveling, especially to the New England area, walking and hiking with his dog, cheering on his favorite sports teams, and has a strong passion for food, cooking, and coffee.

Resource Links: Click on keyword below

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

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