Allina Health 🖮

ALLINA HEALTH RESEARCH

2021 Annual Report



A commitment to research that advances medicine and improves health

With more than 28,000 employees, and 6,000 associated and employed physicians, Allina Health is uniquely positioned to advance research that improves patient outcomes, refines models of health care delivery and enhances population health.

Allina Health Research is broad in its scope, extends across a variety of specialty areas, and is distinguished by its depth, volume of clinical trials, population-based research, data and analytics, and diagnostic studies.

Innovative partnerships allow us to build upon the exceptional work of our Research team. Medical research is an integral piece in our mission to improve the well-being of those we serve. What we learn through research impacts how we care for our patients, the treatments we use, and the way our patients live their lives day-to-day and in the long-term.

To match the comprehensive nature of the care Allina Health provides, we are committed to enhancing and expanding our patient-centered research programs. Our robust research infrastructure continues to serve us well as we aim to solve complex research questions.

On behalf of the Research team, I invite you to learn more about Allina Health Research through this report and online at allinahealth.org.

Badrinath Konety, MD

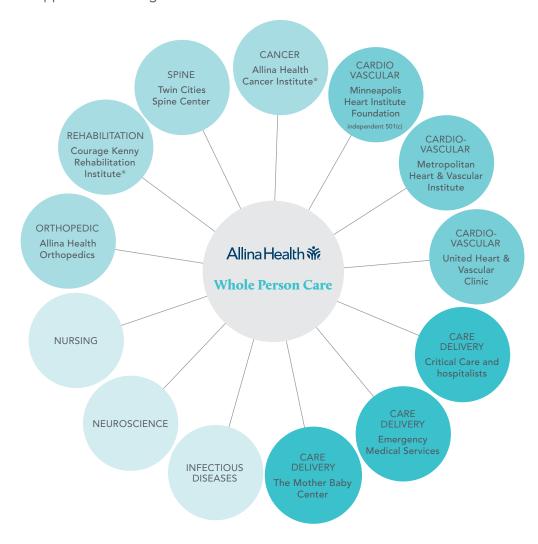
Chief System Research Officer and

President of the Allina Health Cancer Institute

Allina Health

Research areas

Allina Health considers research an essential component of supporting its patients, families and communities. The institutional investment in research provides the necessary infrastructure for advancing research across the organization and fosters a supportive environment for the research community. Research at Allina Health is organized into clinically-focused research houses. This structure aligns with and supports the strategic mission of Allina Health Research Clinical Service Lines.



Allina Health Research supports Allina Health's vision to:

- put the patient first
- make a difference in people's lives by providing exceptional care and service
- create a environment where passionate people thrive and excel, and lead collaborative efforts that solve our community's health care challenges.

Highlighting Accomplishments

Research Grants & Finance

The Research Grants and Finance (RG&F) team ensures compliance with Federal and state government requirements. Key accomplishments for 2021 included:

- No research findings in Single Audit for the third year in a row
- Negotiated increased Facilities and Administration indirect cost rate from 46% to 49%
- Collaborated with Research and other areas to submit 43 applications (increase of 5% from 2020 to 2021)
- Successful tracking of 70 staff reporting time on Federally-sponsored awards (increase of 3% from 2020).

- Secured Federal Government Provider Relief Funding through a COVID Task Force, Phase 4 of \$20 million
- Assisted and supported Mental Health & Addiction in the successful State Opioid Response (SOR) applications related to establishing a Bridge Clinic and Tele-addiction Clinic for \$1.8 million
- Secured an Allina Health Facilities grant with State of Minnesota for car charging stations at Abbott Northwestern for \$60,984
- Secured an EMA grant management in the amount of \$254,188.

Visibility & Diversification

The team increased Research visibility during the pandemic by assisting teams outside of Research to secure critically-needed funding.

 Assisted in the internal Foundation initial submission of 19 applications and 11 budget resubmissions



Read more details about Allina Health Research publications, presentations, media studies and funding by clicking here.

Research Billing

- Research Rate benchmarking project completed; implemented three-year update to all Research Rates
- Launched new Epic Study Remote Monitoring Process for sponsors

Research Billing by the numbers

15 new studies

1,887 hospital research patient visits linked

913 unique hospital patients

Total funding paid to Allina Health facilities for clinical research services:

\$809,000 per hospital/facility

\$114,000 per professional/clinic

Research Contracts

- Implementation of new Allina-wide contracting tool—Icertis; Reviewed and classified more than 1,000 Research legacy agreements
- Developed and implemented the IS Access Agreement for Research ("ISAAR") template for remote monitoring

Research contracts by the numbers

73 new clinical trial agreements (CTAs); 16% increase

300 total agreements—11% increase

15 average total weeks to CTAs

Clinical Research Informatics & Analytics (CRIA)

CRIA participated in a study that had an impact on Whole Person Care and had a direct and immediate impact on patients' lives. The team completed extracts for the Accountable Health Communities (AHC) model—a five-year cooperative agreement with the Centers for Medicare & Medicaid Services (CMS). Patients were screened for health-related social needs (HRSN). Allina then connected patients to community resources based on needs such as housing stability, food insecurity, difficulty paying utilities, access to transportation and interpersonal safety.

CRIA by the numbers

19 number of studies and managed or supported projects by CRIA

52 number of data extracts, prep to research and statistician support

Research Integrity

Allina Health's Research Integrity Office is comprised of the Human Research Protection Program (HRPP), Institutional Review Board (IRB), Research Compliance and Research Conflict of Interest Program. In partnership with the Research community, the Research Integrity Program's mission is to protect and respect the rights and welfare of subjects involved in human research involving Allina Health employees, facilities, patients or data.

In 2021, Research Integrity began pursuing accreditation for its program through the Accreditation of Human Research Protection Programs (AAHRPP) to ensure Allina's Research Integrity program meets AAHRPP's rigorous standards for quality in oversight of human subjects research. The goal is to achieve accreditation in 2023.

Allina Health Cancer Institute Research

Funding Received

\$139,000

in internal Foundation funding

\$1,685,000

in industry-sponsored funding

44

active industry-sponsored studies

- 19 open to enrollment
- 25 in follow-up

Launch of Allina Health Cancer Institute (AHCI)

Allina Health launched the Allina Health Cancer Institute (AHCI) in 2021 to further Allina's commitment to providing fully integrated, Whole Person Care across the entire continuum of cancer treatment. The Allina Health Cancer Institute surrounds patients with connected care, striving to ensure that all members of the care team possess the same level of knowledge about the patient's diagnosis and treatment.

In 2021 Allina Health Cancer Institute added eight new investigators to its research program, including the addition a Solid Tumor Research Medical Director, Christian Squillante, MD, and Hematology Research Medical Director, Fiona He, MD.



Minneapolis Heart Institute Foundation® (MHIF)

MHIF has a 40-year history of world-class cardiovascular research and education that has proven its positive impact on the standard of care for patients around the world. MHIF enrolls hundreds of research participants every year, providing hope through options that may only be available because of research.

MHIF is well positioned to be part of the solution in key areas of cardiovascular health. MHIF's access to a large number of patients and respective data enable MHIF to advance the diagnosis, prevention and treatment across heart and vascular disease. MHIF researchers are experts, with a level of passion and dedication that drives them to seek the answers to important questions.

2021 was a strong year, despite the challenges and realities of the COVID-19 pandemic. MHIF activated more studies in 2021 than in any other year, for the second consecutive year, across all practice areas of cardiovascular medicine and care.

Metropolitan Heart and Vascular Institute (MHVI)

The year 2021 was one of growth and change as MHVI Research continued to address the challenges of COVID. The team worked together to support sponsors by screening and enrolling in coronary studies that remained open to enrollment, and adjusted follow-up visits according to research protocols and COVID restrictions.

MHVI expanded its research repertoire to include a hepatic denervation trial, an LAAO (Left Atrial Appendage Occlusion) trial, a coronary trial with an objective to validate the diagnostic performance of VFR by comparing it against a reference standard fractional flow reserve (FFR), as well as patient registries.

The hepatic denervation trial challenged the group to explore a different type of research and provided the opportunity to collaborate with an endocrinologist. With steady enrollment, 2021 set the stage for the group to be successful for years to come.

- 8 publications with MHVI physicians as authors
- **5** active enrolling sponsored studies
- 2 investigator-initiated studies
- 2 humanitarian-use device studies
- 19 MHVI physicians serving as PI or Sub-Investigator

Echo Core Lab

In 2021, MHIF began supporting Cardiology Research and all industry-sponsored clinical trials were transitioned from the Allina Health Research to MHIF.



Alan Bank, MD, and the Investigator Initiated Research Team secured IP licensing for use of new cardiac resynchronization therapy (CRT) optimization technologies developed in the laboratory. Data

analysis from CRT optimization studies show clinical benefit to patients, especially for those who are characterized as traditional non-responders to CRT device therapy. No other methodology has been able to show a benefit to patients in this heart failure subpopulation. This analysis has driven revisions of clinical CRT optimization protocols at United Heart & Vascular Clinic – St. Paul to promote quality and tracking of CRT patients with a better understanding of device programming and optimization.

United Heart & Vascular Research

\$38,000 received in Grant/Foundation funding
\$207,000 in Industry Sponsored Funding
10 and 4 number of Echo Core Lab Clinical Trials and Investigator Initiated studies

Care Delivery Research

By the numbers

- 49 active studies
- 1,272 active enrollments
- **37** publications
- 29 academic presentations and abstracts
- 3 media appearances
- 8 newly awarded grants
- 24 active grants
- **127** active Allina investigators
- 502,954 patient data used for research

Mother Baby

Allina Health is the largest obstetrical care provider in the state with more than 15,000 babies delivered each year. In collaboration with the service line, Mother Baby research provides scientific, strategic and practical guidance to the development and implementation of research.

Mother Baby research initiatives at Allina Health seek to improve models of care and outcomes during prenatal care, labor and delivery. Research staff are organized under the Mother Baby Research Council, which includes representation from perinatologists, obstetricians and gynecologists, midwives, family physicians, hospital nursing, pediatric hospitalists and Mother Baby service line leadership.

In January, Mother Baby researchers completed a study on self-administered nitrous oxide for labor analgesia and related maternal and neonatal outcome measures and published findings in the Journal of Obstetric Gynecologic and Neonatal Nursing (JOGNN). This is one of a few studies of nitrous use during labor in the U.S., providing information on the patterns of use for labor and outcomes compared to other methods of pain

relief—and the first study in the U.S. to provide examination to a comparison group for these measures.

Throughout 2021, the Mother Baby Research team continued year four of recruitment for the Minnesota-wide universal newborn screening study for congenital cytomegalovirus (cCMV) and enrolled 1,083 additional newborns, totaling 6,899 total recruitments from Allina Health hospital sites since the project began. This study is providing guidance to the Minnesota Department of Health and Centers for Disease Control regarding screening policy and techniques for newborns.

Researchers also collaborated with pediatric intensivists at the University of Minnesota to document experiences of obstetric and pediatric providers when families refuse Vitamin K prophylaxis for newborns to prevent Vitamin K deficiency bleeding. In November, findings were presented at the American Heart Association (AHA) Scientific Sessions from a study evaluating Allina's Cardio-Obstetrics Program. This program and study were conducted in partnership with cardiologists and research staff from the Minneapolis Heart Institute Foundation, and perinatologists from the Mother Baby Clinical Service line. The study identified that under the collaborative care. Cardio-Obstetric Program patients were more closely monitored during their pregnancy, had more tests conducted, and had fewer emergency department and inpatient readmissions postpartum.



Critical Care

The Critical Care Research Program is focused on treatments and outcomes in patients with the highest disease severity cared for in the Intensive Care Units. Optimization of care and outcomes in COVID-19 patients has been one of the program's top priorities. Since 2021, researchers have been working with the Society of Critical Care Medicine International COVID-19 Registry, becoming one of the registry's top case contributors. This work resulted in the opportunity to collaborate with national and international centers on publications addressing outcomes in COVID-19 patients receiving organ support therapies, neurologic manifestations of COVID-19 infection, the association of hypothyroidism with outcomes in hospitalized COVID-19 patients, and hospital variations in management and outcomes of acute respiratory distress syndrome due to COVID-19.

Simultaneously, the Allina Health COVID-19 Research Registry was developed and was instrumental in a recent publication on prognostic factors and outcomes in COVID-19 patients requiring prolonged mechanical ventilation. This study provides clinicians, health care administrators, and patients and families with the real-world local data to inform their decision-making and outcome expectations.

Another important focus of research is care and outcomes of patients receiving treatment with extracorporeal membrane oxygenation (ECMO), resulting in a publication addressing outcomes in patients with septic shock treated with veno-arterial ECMO. The work on outcomes of COVID-19 patients meeting veno-venous ECMO eligibility criteria is ongoing, and the abstract has been submitted to the 2022 Chest Congress. The program is planning to collaborate with the Minnesota ECMO Consortium on the future ECMO-related projects.

Hospitalist

Hospitalists are an integral part of the care team of most hospitalized patients across Allina Health. They are also leaders and partners in safety and quality initiatives. Hospitalist research at Allina primarily focuses on quality and safety outcomes for common medical conditions impacting hospitalized patients. Projects aim to improve patient care by conducting scientific research of care delivery innovations and sharing findings with the larger medical community.

In 2021, the hospitalist team carried out several studies related to outcomes and improving care for patients with documented penicillin allergies (PcnA). Other research has indicated PcnA are over reported and are associated with increased risk of several types of infection. To understand the impact of PcnA labels on outcomes for Allina patients we conducted two studies. First, we examined maternal and neonatal outcomes for pregnant patients hospitalized with positive Group B streptococcus, comparing those with a PcnA label to those without. The researchers found that a PcnA label was associated with a shorter maternal course of antibiotic treatment and a longer neonatal length of stay. Second, the team conducted an observational retrospective cohort study to determine outcomes in hospitalized patients with sepsis and reported PcnA, especially considering the excellent antibiotic stewardship program. Researchers found no difference in key outcomes including inpatient or 30-day mortality in patients admitted with sepsis and reported PcnA compared with patients who reported no PcnA.

In addition, hospitalists collaborated with the Pharmacy team on a study that assessed the effectiveness and feasibility of a pharmacist-led PcnA "de-labeling" process that does not involve laborintensive skin testing or direct oral challenges.

This study found that a pharmacist-led PcnA delabeling process using a standardized checklist is an effective and feasible method for removing PcnA labels among patients without a true allergy; and improved documentation of the allergy history and the information regarding the beta-lactam cross-reactivity serves as a useful tool in selecting safe alternative options in patients with true PcnA. These studies are leading to a larger study on delabeling for patients undergoing surgery at Abbott Northwestern Hospital, with a goal of reducing the occurrence of surgical site infection.



Medical Education

The Medical Education Research Program facilitates investigator-initiated studies by resident and faculty physicians aimed at answering practical and innovative questions on care of hospitalized and outpatient primary care patients. The program includes collaborative research with both the critical care and hospitalist research teams that are closely aligned with medical education.

The Internal Medicine Residency Program at Abbott Northwestern houses the Internal Medicine Bedside Ultrasound (IMBUS) program that leads the nation in internal medicine point-of-care ultrasound education and research. The research program helps facilitate a steady stream of research and publications from within the IMBUS program essential to its international recognition.

The program also provides a facilitated entry to research for resident physicians within Allina Health who are assembling their first IRB application, research study, analyzing data, presenting an abstract at a national conference or publishing their first manuscript. This essential resource aligned with the Allina Care Delivery Research team allows new

physicians to efficiently learn and perform research during residency, and to also understand the research and publication process early in their careers. It adds value to Allina Health's physician residency programs and prepares a new generation of research-savvy clinicians, many of whom stay within or return to Allina Health for careers after their residency.

Many local, regional and national research presentations came out of the program despite the limitations of the COVID-19 pandemic, and many manuscripts were published. Of note, the multi-year, 44,000 patient study demonstrating the positive patient and system impacts of a hospital-wide point-of-care ultrasound program (IMBUS) was completed this year and is expected to be published in the fall of 2022. This novel and innovative study is a collaborative effort between the Internal Medicine Residency Program at Abbott Northwestern, Abbott Northwestern General Medicine Associates (ANGMA), the Abbott Northwestern Foundation and the Allina Health Care Delivery Research team for the past eight years.

Emergency Medical Services (EMS)

Allina Health EMS is one of the largest ambulance services in the Upper Midwest, with more than 500 care providers and approximately 130,000 service calls annually across 120 communities in Minnesota and western Wisconsin. The agency provides a wide array of services including emergency medical dispatching with pre-arrival instructions, 911 ambulance response, scheduled critical care/ALS/BLS transports, wheelchair transports, EMS education and community paramedic care.

Emergency Medical Services (EMS) research aims to improve the delivery and outcomes of the prehospital care provided by our ambulance service and 911 dispatch center. Since 2011, a small but active group of core investigators has been conducting investigator-initiated research on topics such as management of cardiac arrest,

community paramedicine, response vehicle design and safety, EMS provider well-being, prehospital pain management, sepsis recognition and mental health emergencies. Investigators present research annually at the scientific sessions of the National Association of EMS Physicians, the premier forum for sharing prehospital medicine research with an international community of EMS stakeholders.

Studying the Well-Being and Care of Emergency Responders

EMS work takes an emotional toll on dispatchers, EMTs and paramedics, and today's EMS workforce is facing unprecedented challenges. Extraordinary call volumes and increased stress brought about by the COVID-19 pandemic, a national, crisis-level shortage of EMS workers and an ever-increasing number of EMS calls involving mental health crises make a focused commitment to EMS provider wellness more important than ever.



The immense challenges of recent years have brought a renewed focus on studying how well our EMS workforce is faring at Allina."

Lori Boland

Allina's EMS leadership has taken a progressive approach to implementing novel initiatives to increase support for its providers, including embedding EMS chaplains to provide 24/7 support for EMS clinicians, sponsoring resident EMS therapy dogs at ambulance bases, and providing 911 dispatchers with resiliencWe and skills training to help them better cope with and manage calls involving patients experiencing mental health emergencies.

This expansion of provider support resources has

been accompanied by a strategic focus on EMS provider well-being research. In recent years, EMS investigators have assessed professional burnout and studied its association with provider characteristics, exposure to critical incidents and coping styles, and conducted a qualitative study using paramedic focus groups to better understand the unique stressors associated with pediatric emergencies.

In 2021, the Allina Health EMS Wellness Advisory Committee launched its newest provider support resource, an EMS Peer Support Team, and investigators received grant funding to study its impact. As part of the study, a baseline survey of all EMS staff was conducted in October 2021 and results show professional burnout continues to increase in this provider group.



The EMS research team also began to develop a protocol for a small pilot study which will examine the impact of the EMS therapy dogs on the heart rate variability of clinicians. "The immense challenges of recent years have brought a renewed focus on studying how well our EMS workforce is faring at

Allina", says Lori Boland, principal research scientist for Allina Health EMS. "It is paramount to the health and safety of our communities, and communities across the country, that we continue to improve our understanding of how to best support this integral part of our nation's corps of emergency responders."

Infectious Diseases Research

In 2021, Allina Health Infectious Diseases Research included the National Institutes of Health REPRIEVE study and the Janssen ENSEMBLE trial of COVID-19 vaccination.

REPRIEVE is the largest randomized trial to date

in HIV and results from REPRIEVE will help clinical researchers and clinical care providers to develop heart disease prevention and treatment guidelines, specifically for people with HIV. The trial is evaluating if a statin medication called pitavastatin calcium is effective to prevent heart disease among people with HIV. The trial includes more than 7,500 participants at 100 clinical research sites across the globe.

Allina Health is a research site for the Janssen ENBEMBLE trial for the randomized, doubleblind phase 3 study to assess the effectiveness of COVID-19 vaccination. In 2021, a total of 1,375 specimens (saliva specimens, nasal swabs and blood specimens) were collected by Allina Health researchers and processed for the ENSEMBLE trial.



In 2021, Frank Rhame, MD, Infectious Diseases physician at Allina Health Uptown Clinic and Abbott Northwestern Hospital, completed:

20 presentations

54 media appearances,

3 number of published articles in Infectious Diseases publications

7 number of student mentoring at University of Minnesota Process of Care Clerkship (POCC) medical students.



Infectious Diseases is the least predictable of all medical specialties and the COVID pandemic has illustrated the challenges of a concrete enemy evolving to escape our treatments. Evolution is a powerful force.

— Frank Rhame, MD

Neuroscience Research

Neuro-Interventional Radiology

In 2021 Neuroscience Research completed participation in a five-year MicroVention Woven EndoBridge (WEB-IT) clinical trial. This novel intravascular brain aneurysm treatment device was approved by the FDA in late December 2018 and has now been implanted in more than 60 percent of the patients treated at Abbott Northwestern Hospital since February 2019. When patients are treated with the WEB device, their hospital stays are shorter with fewer complications, and they can often return home within 24 hours. The research shows that the WEB device provides physicians with a safe and minimally-invasive treatment option for patients who might have otherwise required open surgical clipping of their aneurysm.

Neuro-Oncology

The Neuro-Oncology team participated in five clinical trials in 2021 including a trial to evaluate multiple regimens in newly diagnosed and recurrent glioblastoma (GBM AGILE). The AGILE trial, which uses a unique, adaptive, study protocol and seamless phase II/III design, contains three treatment arms and a control. Focused on identifying effective therapies for glioblastoma and matching them with patient subtypes, the AGILE trial allows the Neuro-Oncology team to provide optimal care to our patients. Two additional treatment arms are expected to open in 2022. Across all Neuro-Oncology studies in 2021 the team consented 25 participants and enrolled 15 participants. Studies included one device, one surgical implant and five investigational drug agents.

Stroke

The Stroke team participated in five clinical trials in 2021, including the ARCADIA trial, an investigation of Apixaban (Eliquis) vs. Aspirin for cryptogenic stroke, which represents about one-third of cases. In these cases, Apixaban may be more effective for future stroke prevention. While participating in ARCADIA, patients are given study medication and

followed for up to 84 months. United Hospital was a top five enrolling site for the ARCADIA study in 2021, with 13 patients actively randomized on the trial. In 2022, the Stroke program anticipates adding Mercy Hospital and merging into one Neuroscience Institute site. Across all 2021 stroke studies, five patients were enrolled, and 27 patients had their information used in research projects.

Orthopedics Research

The Orthopedics Research team underwent changes in staff and scope in 2021. In addition to wrapping up several studies, efforts were made to expand industry-sponsored device studies, pursue partnerships with PCORI investigators and facilitate orthopedic trauma research within Allina Health. The staff addressed new challenges in supporting the research within the Mental Health/Addiction Services department as part of two grants funded by the Minnesota Department of Human Services.

Analysis was completed and submitted for presentation on a pilot case series by Aimee Klapach, MD, of two-stage revision anterior cruciate ligament reconstructions for subjects with widening of bone tunnels. The abstract has been accepted for podium presentation at the Mid-America Orthopedic Society in 2022. Use of bone graft substitute continues to be assessed as new products are introduced to the market, but radiographic evidence appears to demonstrate sufficient integration with no complications in this series. Further evaluation, including prospective enrollment using new products, is being assessed.



Courage Kenny Rehabilitation Research

MNSCIMS

In May of 2021, Courage Kenny Research (CKR)/
Allina Health partnered with the University of
Minnesota, Mayo, Regions Hospital/Health Partners,
Hennepin Healthcare and community spinal cord
injury (SCI) advocacy groups to develop a federal
grant to be designated as one of 14 U.S. spinal
cord model systems of care that receive five-year
research funding from the U.S. Department of Health
and Human Services National Institute on Disability,
Independent Living and Rehabilitation Research.

In September 2021, the Minnesota Regional Spinal Cord Injury Model System was notified it was selected for funding, which represents an extraordinary achievement for Minnesota rehabilitation researchers and more importantly, an important opportunity to expand innovation and new knowledge development in the service of people with SCI living in Minnesota, North and South Dakota, and Wisconsin.

Over the next five years, Courage Kenny Rehabilitation Institute and Courage Kenny Research will be involved in collecting data on all new traumatic SCI patients beginning with admission to inpatient rehabilitation and then for years of follow-up. Courage Kenny Research will also be involved in an across-institution randomized controlled trial to evaluate use of brivaracetam to reduce neuropathic pain in chronic SCI and in a cross-sectional, observational study to determine whether meeting SCI Physical Activity Guidelines is associated with health-related and psychosocial outcomes.

Objective Dual-Task Turning Measures for Return-to-Duty Assessment

Since 2007, investigators with the Courage Kenny Research Center have been involved in militarycivilian partnerships with both fellowships and grants to facilitate best practice assessments and interventions for Service members that have sustained a concussion or mild traumatic brain injury to facilitate safe return to duty. This work, which is relevant for both Courage Kenny patients/civilians and active-duty service members is currently focused on development and validation of outcome measures that can identify subtle deficits that may hinder safe and effective return to full duty, sport or other activity. In the current grant (Objective Dual-task Turning Measures for Return-to-Duty Assessment) which runs through September 2023, researchers are working to advance and validate the use of wearable inertial sensors in dual-task (combining cognitive and motor) assessments involving turning at different speeds and angles for identifying lingering deficits, and to follow improvement after rehabilitation interventions.

Twin Cities Spine

The Twin Cities Spine Research Program remains active and vibrant as it investigates the natural history of spine disorders, evaluates operative and non-operative treatments using clinical and radiological outcomes, tests diagnostic measures, and evaluates value by way of costs and outcomes data. The team publishes manuscripts in leading peer-reviewed spine journals and continues to present findings at national and international spine society meetings. Twin Cities Spine surgeons and physician assistants are engaged with community and allied health care groups and are members of national and international spine and orthopedic societies.

By the numbers

25 active studies including:

- 18 retrospective research studies
- 6 prospective research studies
- 1 biomechanical research study



Research Administration 2925 Chicago Avenue Minneapolis, MN 55407

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