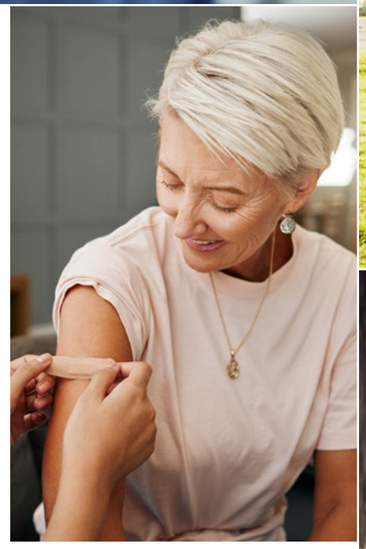
CommonSpirit

Together we succeed.

CommonSpirit Health Research Institute

2024 ANNUAL REPORT



Contents

Welcome

Welcome to the third Annual Report of CommonSpirit Health Research Institute. This report highlights the transformative research conducted by our teams of researchers, clinicians, and staff members.

In FY24, the Research Institute aimed to align with CommonSpirit's overall mission: fostering unity among our teams, processes, and resources to achieve One CommonSpirit. This unification enhances our efficiency, cooperation, and processes, building a culture of collaboration and shared knowledge.

A key achievement in the past year has been integrating our Mountain Region colleagues from Centura Health. They have become valuable partners, bringing extensive clinical research expertise. This transition has been seamless, offering mutual benefits.

We are enhancing our national research leadership to better serve care sites, clinicians, and patients. We have initiated an optimization process for the research start up which will streamline the research process tremendously. The Office of Research Integrity has standardized IRB policies, fostering greater collaboration and support. Additionally, a multi-departmental group, including research institutes, philanthropy, accounting, and national grants, has unified efforts to pursue and manage grants from a national perspective.

Health equity remains a strategic focus. We are partnering with the Lloyd H. Dean Institute for Humankindness and Health Justice and industry leaders to address health and research disparities.

Our academic institutions lead in innovation and excellence. Baylor College of Medicine has established data agreements, Morehouse School of Medicine secured a prestigious, large grant, and Creighton University School of Medicine hosted Research Institute leadership to explore future growth opportunities.

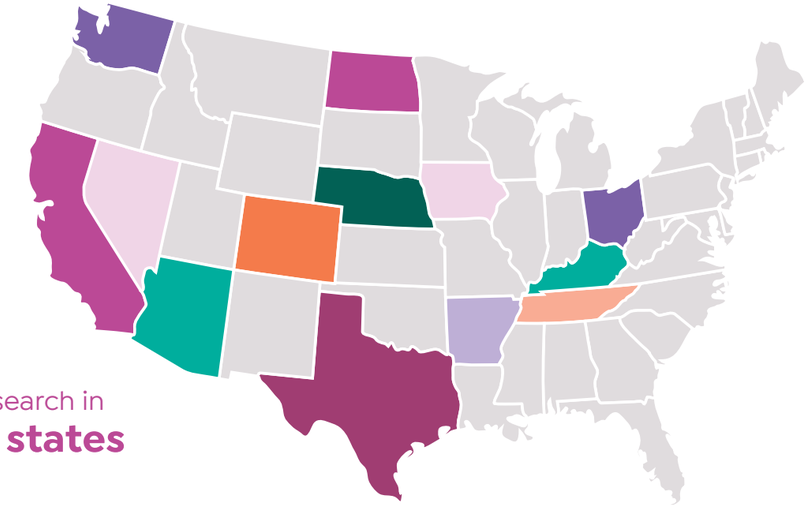
Looking ahead, we are planning our next Research Summit for early 2025. We extend our gratitude to the many teams within the Research Institute, as well as our collaborators and academic partners, for their dedication and commitment. Despite constant change, their resilience and collaborative spirit continue to create new opportunities to transform care.

Please enjoy this in-depth look at their work.

Vani Nilakantan, PhD
System Vice President, Research
CommonSpirit Health
Research Institute

Robert Wiebe, MD, MBA, MPH
Ex Officio Board Member
Executive Vice President and
Chief Medical Officer

Research at CommonSpirit Health



Research in
13 states

40
Teaching
Facilities

Active Prospective
Clinical Trials:
499

Active Data
Collection Protocols:
250

Participants in
Clinical Trials

Total Enrolled (Active Trials): **2,891**
Total in Treatment (Active Trials): **507**
Total Enrolled in Last 12 Months: **597**

Our National Presence

CommonSpirit Health delivers clinical excellence throughout the country, with 35,000 providers and 45,000 nurses caring for patients at more than 2,200 sites.

CommonSpirit Health Research Institute is a vital part of this ministry, performing clinical work at universities, hospitals and clinics in urban and rural communities.

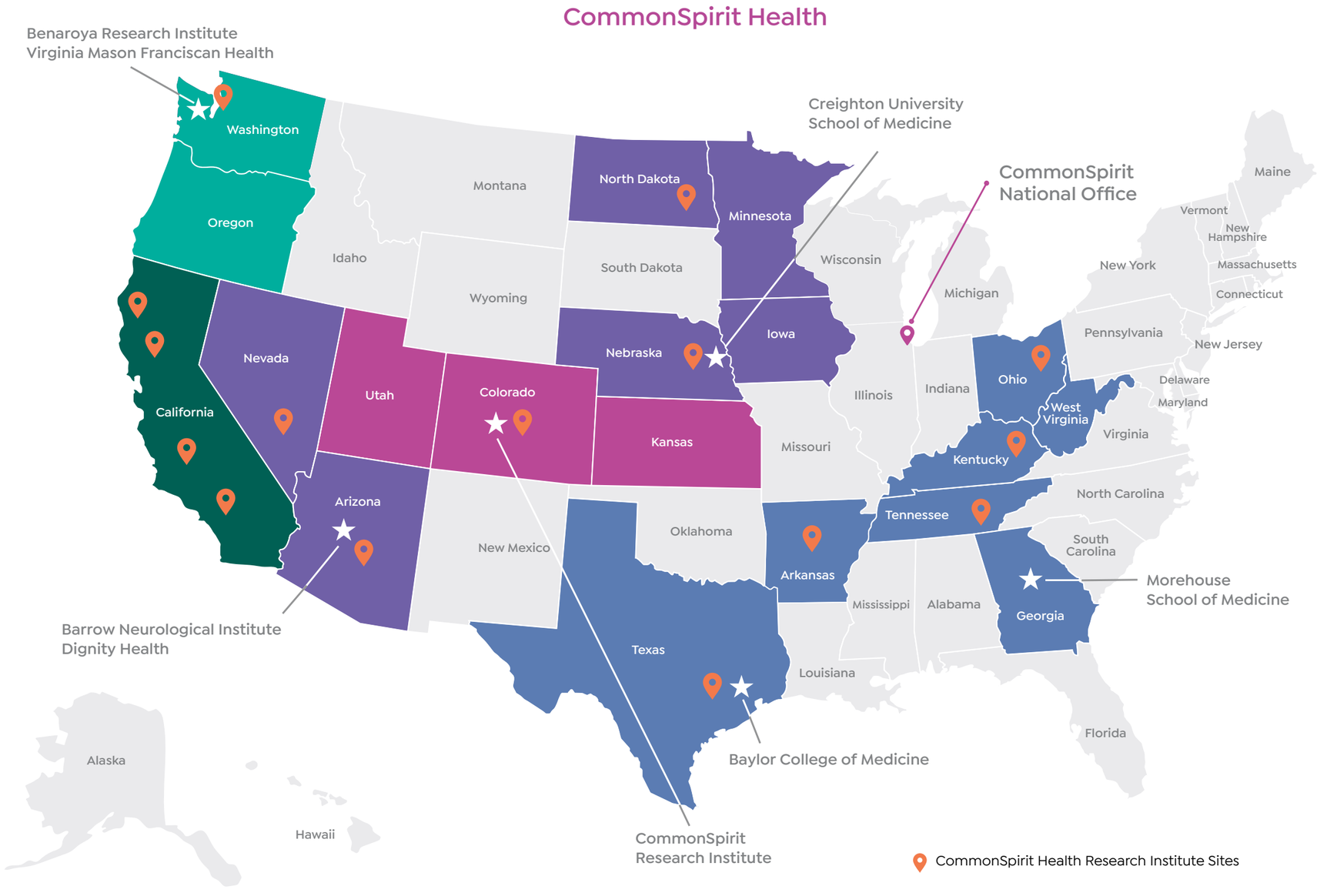
CommonSpirit Health Research Institute is a nationally recognized leader in innovative research, transforming health care for the communities we serve. Pursuing research, innovation and discovery with the goal of finding new ways to provide timely and effective treatment for patients is our fundamental value.

We believe research provides opportunity – an opportunity to find a cure, an opportunity to improve quality of life, an opportunity to improve health care for the next generation, and an opportunity to provide access to health care for all regardless of race, gender or socio-economic status. Connecting patients with this opportunity is a basic tenet of *humankindness.*

During FY24, CommonSpirit Health transitioned to a new geographic organization of the ministry locations, using five regions as the anchor points. Within these five regions are many markets consisting of hospitals, clinics and other health care services. CommonSpirit Health Research Institute is proud to have a presence within each of the regions and many of the markets.

CommonSpirit Health Regions

- **Northwest:** Oregon, Washington
- **California**
- **Mountain:** Colorado, Kansas, Utah
- **Central:** Arizona, Iowa, Minnesota, Nebraska, Nevada, North Dakota
- **South:** Arkansas, Georgia Kentucky, Tennessee, Texas, Ohio and West Virginia



Who We Are

Contracted to provide services to all CommonSpirit Health community hospitals and clinics, CommonSpirit Health Research Institute follows a standard research review and approval process for all facilities engaged in research. The Research Institute manages this process when any research endeavor requires access to CommonSpirit patients, patient data, employees, medical staff, health care services and/or use of our campuses.

Research by the Numbers

Active Prospective Clinical Trials: **499**

Active Data Collection Protocols: **250**

Study Sponsors: **116**

Research Areas: **27**

Active Clinical Sites: **78**

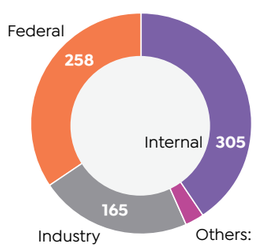
Research Activity by Region:

California	26%
Central	17%
Mountain	24%
Northwest	12%
South	21%

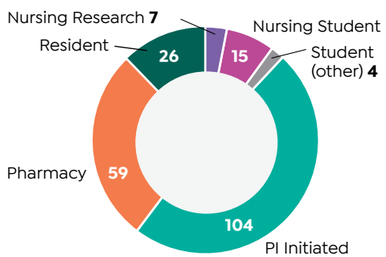
Top Three General Therapeutic Areas:

1. Oncology
2. Cardiology
3. Neurology

Sponsor Type
(Active Studies Only)



Data Studies by Research Area



CommonSpirit Health Research Institute | Shared Services

Office of Research Finance and Accounting — LINK

Melissa Aigner System Director

Support
- Financial Clinical Trial compliance oversight, which is a focus of the OIG
- Research Clinical Trial Budget Management & Negotiation
- Medicare Coverage Analysis (MCA)
- Clinical Trial Research Revenue Cycle Management
- Clinical Trial Financial Reporting
- Operational Finance
- Signal Path Finance

Office of Research Integrity and Quality — LINK

Russell Stolp, IRB System Manager, and **Lauren Bacon**, QA System Manager

IRB
- Federal Wide Assurance
- IRB (internal and external)
- Privacy Board Reviews
- IIR, GME and Student Research

Quality Assurance
- COI Reviews
- Post Approval Monitoring
- NCORP Monitoring
- CAPA
- Regulatory Affairs

Training and Education
- Staff Training and Onboarding
- CITI
- Education
- Policies and Procedures

Office of Research, Sponsored Programs, Grants and Contracts — LINK

Julie Link, System Director, and **Terah Hardcastle**, System Manager, Research Programs

- Master CTAs/Agreements
- Single site CTAs/Agreements
- Just In Time Contracts
- Comprehensive Contracting Services (DUA, BAA, CDA etc)

Grants
- Research Grants
- Federal Grants
- Foundation Partnership
- Policies and Procedures

NCORP
- Program Management
- Centralized Regulatory
- Centralized contracting
- Infrastructure

Research Analytics Center for Excellence (RACE) — LINK

Vino Raj, MD, System Director Research Analytics

Data Support Tools
- CTMS
- REDCap
- PI Tools Analytics
- Statistical Tools
- Clinical Trial Operation Insights

Data Lakes for Research
- Data Extraction
- ETL and Governance
- Registry Integration

AI and Machine learning
- Automation of Data Extractions
- NLP and ML Studies
- Clinical Data Mapping

Office of Research Operations — LINK

Mary Rydman and **Jared Rowe**, System Directors

Research Site Operations
- Research Managers
- Research Coordinators
- Participant Enrollment
- Compliance to SOPs
- Investigator Support
- CTMS Implementation

New Business Development
- Preliminary Clinical Trial Feasibility
- Recruitment of PIs
- Study Implementation with New Site

Office of Research Finance and Accounting

CommonSpirit Health Research Institute's Office of Research Finance and Accounting successfully secured funding for 33 new project/study budgets in FY24 and managed post-award budgets for 265 industry studies and 363 NCORP research studies.

The team manages financial clinical trial compliance oversight, budget management and negotiation, Medicare coverage analysis, revenue cycle management, and financial reporting for all research operations.

Sponsor Payments Received:

$1.5 Million

Budgets Completed in FY24:
25

Budget Staff (FTEs):
2

Budget Turnaround Time Goal:
90 days

Average Length of Budget Process:
90 days

FINANCE AND ACCOUNTING TEAM PROVIDES VITAL SUPPORT

Before a CommonSpirit Health-funded clinical research trial can begin in a clinic or office, it must first spend time with the Office of Research Finance and Accounting team — about 90 days, on average.

"This year, we formulated and managed budgets for approximately 33 trials," explains Melissa Aigner, System Director Research Finance. "Our goal is to provide a 90-day turnaround for budgets — some are done quicker but some take much longer."

The budgeting process is complex and precise. The team's Senior Financial Analysts begin by analyzing the protocol and schedule of events, assessing line by line to create a standard budget document.

"We've created standard time allocations for many items, including the interactions a coordinator must have with a patient," she explains. "The budget must reflect every blood draw and EKG, each medication review, labs that need to get sent out for a specific provider for the sponsor, when there is a need for something like dry ice... Once the budget reflects every single item, we negotiate with the sponsor."

That process can be lengthy and includes multiple layers of review. One way research managers can assist is by completing a budget checklist, a tedious but necessary tool for the Finance team.

"The checklist is another tool that allows us to better support our growing pool of research managers and investigators," Melissa says.

She is grateful for the work her team does to support research teams throughout the ministry. "We are behind the scenes, ensuring operations can keep doing trials."

In recent years, the number of researchers Melissa Aigner and her team serve has grown, leading them to implement tools and processes to better standardize the budget process.

Melissa Aigner

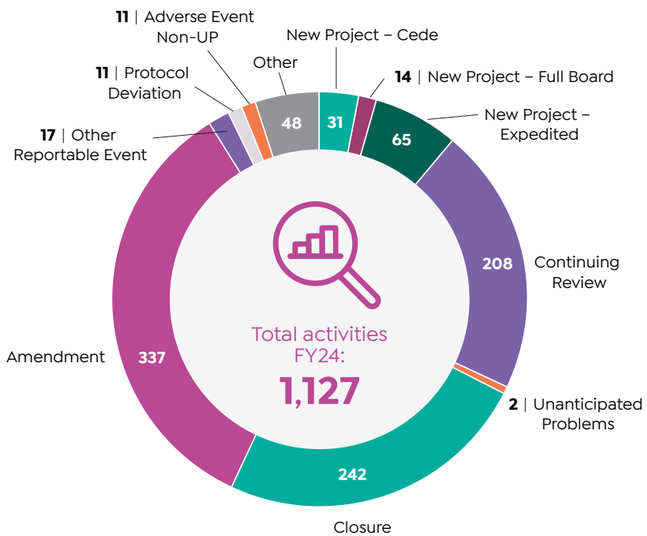
System Director Research Finance, CommonSpirit Health Research Institute

Office of Research Integrity and Quality

The CommonSpirit Health Research Institute Office of Research Integrity and Quality oversees training and education, quality assurance, and IRB management for the enterprise. In FY24, the team increased training and education opportunities in recognition of the growth of the organization and the introduction of new staff and investigators throughout the CommonSpirit ministry.

IRB Management

In FY24, the CommonSpirit Health Research Institute IRB team maintained an impressive average turnaround time of less than five days for complete submissions. The team also updated research procedures and developed updated IRBNet Smart Forms, which are currently being programmed by IRBNet. They conducted this work while also consolidating overarching research policies with CommonSpirit teams in Arizona.



IRB OFFICE HOURS: ONE-ON-ONE EDUCATION OPPORTUNITIES PROVIDE INVALUABLE SUPPORT

In FY24, the Office of Research Integrity and Quality's Research Integrity and Compliance team recognized and responded to the need for increased and diversified IRB support. This need has increased in recent years as CommonSpirit Health has grown and added clinicians and facilities, leading to growth in the community of investigators and staff members working within the Research Institute as well.

As part of their increased support opportunities, the team offers twice weekly Office Hours, open to anyone in need of one-on-one support.

The sessions use Zoom technology, including breakout rooms for privacy, which ensures the Integrity and Compliance team is able to interact with people across the country, sharing screens and engaging in individual, private conversations.

"When a new coordinator or researcher comes on board, we invite them to Office Hours," explains Allison Griffin, MS, CIP, IRB Program Specialist. "We can walk them through IRBNet, show them the resources available to them, and just make sure they have what they need moving forward."

Attendees share that the one-on-one Office Hours provide an opportunity for education that is more thorough and responsive than an email exchange, while ensuring that they understand the CommonSpirit process and procedures.

"We provide support during any stage of the study implementation process, from pre-initiation through closure."

Allison Griffin

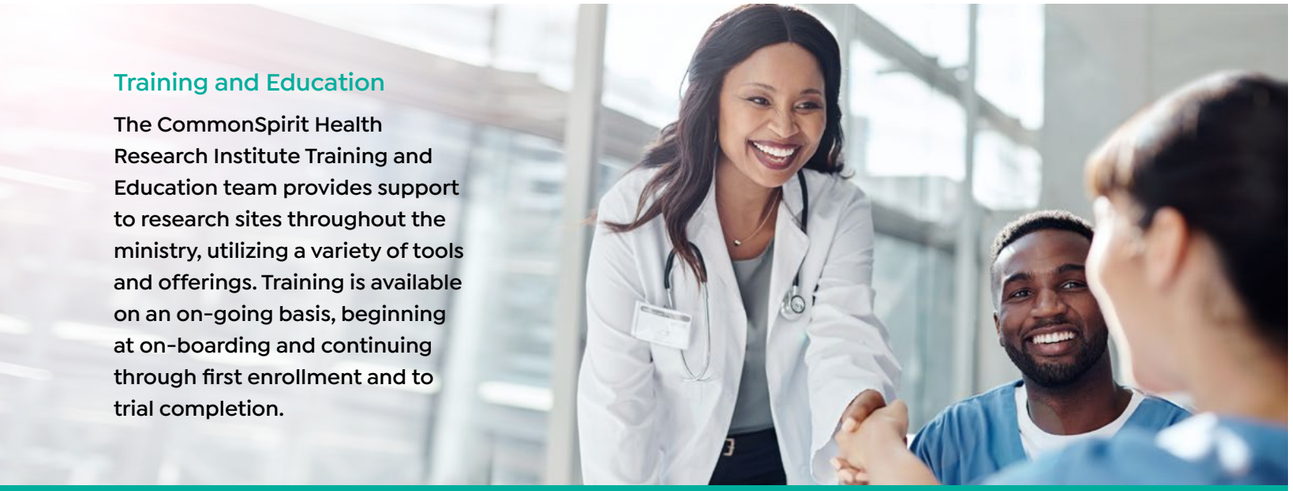
MS, CIP, IRB Program Specialist

NCORP Fundamentals Program: Ensuring Success

In response to the specific needs of NCORP trials, the Training and Education team implemented a NCORP Fundamentals Program, a 20-hour course covering ten different topics shared in a hands-on, focused training.

On average, coordinators who went through the program increased their scores by six percent overall. Specifically, new hires that went through the program increased their scores on average by 12 percent. Coordinators increased their NCORP specific-scores (questions based specifically on NCORP-related topics) on average by 16 percent after completing the program, and new hires increased their NCORP-specific scores on average by 33 percent after completing the program. This shows that upon graduating from the NCORP Fundamentals Program, coordinators have a significantly improved foundation and skillset to their work moving forward.

Next year, Training and Education's goal is to develop a Train-the-Trainer program to empower sites to hold training of their own eventually. The team will also conduct annual training audits to support managers and staff identify potential training gaps and mitigate them proactively.



Training and Education

The CommonSpirit Health Research Institute Training and Education team provides support to research sites throughout the ministry, utilizing a variety of tools and offerings. Training is available on an on-going basis, beginning at on-boarding and continuing through first enrollment and to trial completion.

Onboarded: **23 NEW STAFF/ INVESTIGATORS**	Total CEU Opportunities Provided: **5**	Total policies/procedures updated/created: **5**
Total projects completed: **3**	Total Job Aids/Quals Created and Deployed: **20**	Total support for IRBNet: **AVERAGE 15 REQUESTS PER MONTH**

QUALITY ASSURANCE PROGRAM: FIRST ENROLLMENT REVIEW LAYS STRONG FOUNDATION

The Office of Research Integrity and Quality's Training and Education team has developed an innovative tool to support a gap in monitoring for trials within the National Cancer Institute. The project has shown resounding success.

"NCI trials have not been historically monitored the same as an industry trial would be," explains Lauren Bacon, Systems Manager Research Integrity, Quality Assurance. "By providing a first enrollment review, we are able to have our CommonSpirit Research Institute Quality Assurance review the enrollment, engaging the research coordinators with the internal monitoring and support that is so effective in addressing issues and improving compliance over time."

In FY24, the QA team saw a 50 percent reduction in the number of findings between the coordinator enrollment review reports when comparing their first to their most recent.

"This reduction indicates that coordinators are becoming more proficient in their roles, better understanding the complexities of NCI trials, and adhering more closely to established guidelines and procedures," Lauren says. "It also reflects positively on the support and training provided by our department and the organization as a whole, demonstrating a commitment to continuous improvement and maintaining high standards of quality and compliance. These findings are a testament to the success of the efforts put into supporting and monitoring coordinator enrollment activities, ultimately leading to better outcomes for participants and the overall success of the NCI treatment trials."

"The efforts put into supporting and monitoring coordinator enrollment activities ultimately lead to better outcomes and overall success of the NCI treatment trials."

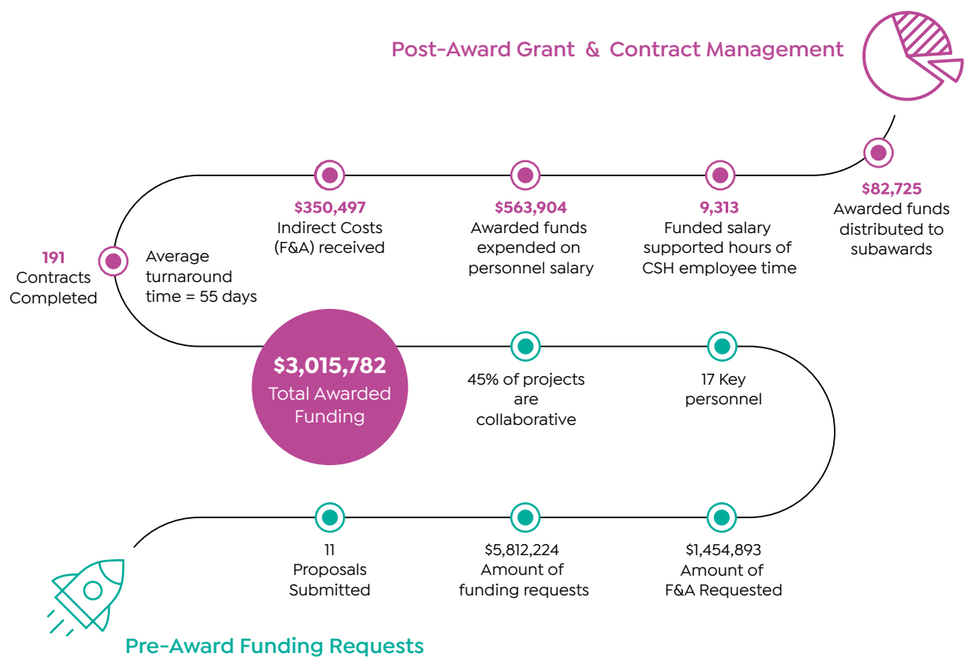
Lauren Bacon

Systems Manager Research Integrity, Quality Assurance

Office of Research Sponsored Programs, Grants and Contracts

The Office of Research Sponsored Programs, Grants and Contracts, supports research across the CommonSpirit Health ministry. The team's mission is to empower researchers by securing external funding, driving innovation, and improving patient outcomes through administrative excellence.

Total Number of Completed Contracts: **191**



SUPPORT

CONTRACT SUPPORT VITAL TO CLINICAL RESEARCH COMPLIANCE AND EFFICACY

The work of the Sponsored Programs, Grants and Contracts team lays the foundation for successful research initiatives. Through their work, they provide pre-award grant support, contracting support, and connections with internal and external partners, including academic partners.

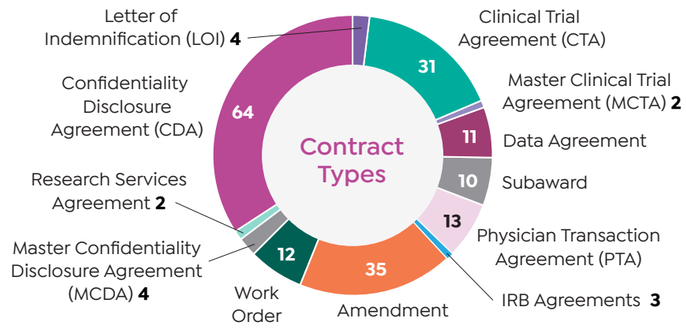
Once a submission to the contracting team is submitted, it undergoes thorough review and analysis, before eventually being finalized and signed.

"All research-related contracts throughout the Research Institute must go through our team," says Rita Lerner, CCRP, Program Specialist, Research Contracts. "The support of the contract team allows researchers and partners to continue making significant strides in advancing health care and driving innovation."

Rita Lerner

CCRP, Program Specialist, Research Contracts

In the post-award phase, the Sponsored Programs, Grants and Contracts team continues its crucial role by implementing financial grant management, internal controls, tracking time and effort reporting, managing travel and procurement, and providing comprehensive reporting for project monitoring.



Research Analytics Center of Excellence (RACE)

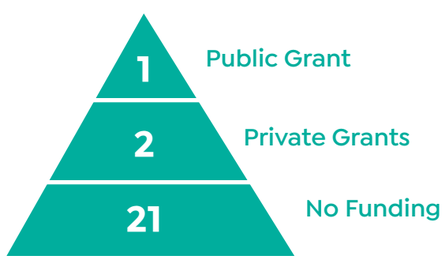
In FY24, the CommonSpirit Health Research Analytics Center of Excellence (RACE) made significant strides in enhancing research capabilities and fostering synergy across our ministry. Officially in existence for two years, the small but dedicated team of four, including a new project manager for our PCORI program and a dedicated data research specialist, has been pivotal in driving our mission forward.

Project Types

Total Redcap Requests: **25**

Independent: **2**	Prospective: **6**	Single site: **4**
Multi-Site: **7**	Registry: **7**	QI: **13**
Academic: **3**	Retrospective: **12**	Evidence-Based: **7**

RedCap Project Funding



REDCAP: A CATALYST FOR ONE COMMONSPIRIT

REDCap has been instrumental in our quest to unify and streamline research efforts. This versatile platform has empowered our researchers to design, manage, and analyze studies with ease and precision. Over the past year, we have seen a substantial increase in REDCap usage, with 25 total requests and significant contributions across various specialties including trauma research, pharmacy, neuroscience, and more.

REDCap's user-friendly interface and customizable features have simplified data collection and management. Researchers can easily create and deploy surveys, track patient outcomes, and manage large datasets. This streamlined approach has reduced administrative burdens and allowed our team to focus on critical research activities, ultimately improving the quality and efficiency of our studies.

"Our team leveraged REDCap to develop comprehensive dashboards and registries, including the TAVR Registry," explains Vino Raj, MD, MBA, System Director Research Analytics. "This registry integrates data from multiple sources and provides real-time insights into patient demographics, procedure outcomes, and long-term health status. Data visualizations from platforms like Google Looker, Tableau, and Power BI empower decision-makers, driving quicker insights and fostering a data-driven culture."

REDCap's secure platform protects sensitive data while allowing authorized users to share information seamlessly across sites.

"Collaboration is at the heart of research initiatives," Dr. Raj says. "REDCap facilitates seamless cooperation among researchers, clinicians, and stakeholders. This capability is crucial in multi-site studies where coordination and data integrity are paramount."

"Collaboration is at the heart of our research initiatives. REDCap supports that."

Vino Raj, MD

MBA, System Director Research Analytics

RACE: ACHIEVEMENTS AND CONTRIBUTIONS IN FY24

Growing REDCap Utilization:
With 25 requests, REDCap is now central to our data collection and management strategies.

Expanded Project Support:
Delivered substantial assistance to PCORI programs and scholarly research initiatives across the ministry.

Advanced Analytics Services:
Dedicated more than 240 hours to analytics services and registry/dashboard builds, enhancing data-driven decision-making processes.

Enhanced Support for Data Research Studies:
Provided dedicated support for data research and scholarly studies within the ministry, driving innovation and improving research outcomes across various departments.

In 2024, the RACE team contributed over 500 hours to supporting various funded research studies. Their commitment to high-quality data management and analysis has provided insightful findings that have driven research progression across the ministry.

THE WAY FORWARD: LEVERAGING LEAN THINKING TO OPTIMIZE DATA

RACE is committed to further optimizing data processes through lean thinking principles. Strategic priorities include:

Simplifying Data Systems:
Our goal is to unify tools and platforms, reduce redundancy, and streamline data processes.

Building Predictive Analytics:
Investing in predictive analytics will allow us to anticipate needs, trends, and issues, enabling preemptive action and aligning with lean principles of efficiency.

Strategic Priorities

Empowering Decision-Makers with Data:
By decentralizing data access, we empower employees at various levels to make data-driven decisions quickly without waiting for higher-level approvals.

Continuous Improvement of Data Practices:
Establishing continuous feedback loops will enable regular refinements and adjustments to data practices based on real-time outcomes and feedback.

RACE Services

115 | **Hours of Analytic Services**

240 | **Registry & Dashboard Builds**

A UNIFIED VISION FOR A HEALTHIER FUTURE

RACE is committed to fostering innovation, collaboration, and excellence. By strategically utilizing REDCap and lean methodologies, RACE is enhancing research capabilities while advancing our broader mission of improving health and promoting social justice. As we continue to navigate the complexities of health care research, RACE stands as a testament to what we can achieve when we work together towards a common goal.

Office of Research Operations

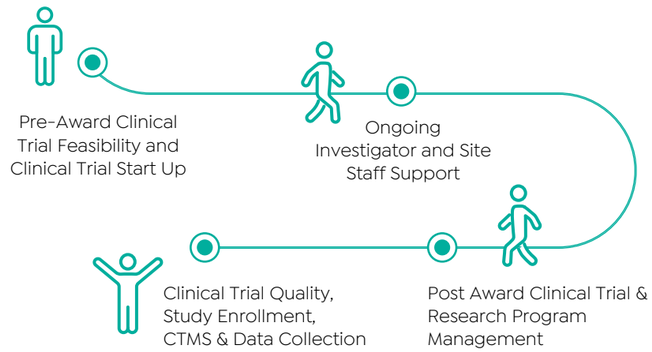
CommonSpirit Health Research Institute's Office of Research Operations managed nearly 500 active clinical trials in FY24, with a keen eye on alignment and standardization across our national, regional and site level research operations. The team of 74 FTEs provides support from trial feasibility through to data collection and completion.

During FY24, the Operations team assisted with the introduction of legacy Centura investigators and staff to CommonSpirit Health, facilitating an exchange of knowledge and experience while also instituting standardization of policies and procedures to streamline our workflow which now supports an even larger footprint.

74 FTEs Total

- **2** System Directors
- **9** Market Managers
- **63** On-Site Research Clinical Coordinators

Primary Research Operations Functions



499 Active Clinical Trials

2,891 Active Study Participants

RESEARCH INSTITUTE TEAM MEMBERS RECOGNIZED AS INDUSTRY LEADERS

CommonSpirit Health Research Institute's Office of Research Operations supports the growth and development of the Institute's most valuable resource – its people. A vital part of that support is enabling our team members to have the opportunity to collaborate with other thought leaders in the industry.

Marlyn Molero, CommonSpirit Health Clinical Research Associate at the Mission Hope Cancer Center in Santa Maria, California, was appointed as Vice-Chair of NRG Oncology's Patient Advocate Committee (PAC) in June 2024. NRG Oncology is part of the National Cancer Institute's (NCI) National Clinical Trials Network (NCTN). The group is focused on improving outcomes for adults with cancer through multi-center clinical research. Marlyn is also a member of the NRG Gynecologic Oncology Committee.

For Marlyn, the opportunity to be a voice in the broader world of clinical research gives her the opportunity to affect change and represent CommonSpirit.

"I'm passionate about closing the gap between research and patients, particularly within the Latino community," Marlyn says. "As a Patient Advocate, I collaborate to make clinical trials more accessible and fair, ensuring that all patients, regardless of language or background, have the chance to benefit from the latest cancer research."

Through her work with the CommonSpirit Health Research Institute, Marlyn has seen firsthand the effect collaboration among leading research scientists can have on patient care.

"Working with CommonSpirit Health Research Institute has shown me the impact that collaboration among top scientists can have on patient care," Marlyn says. "I'm proud to be part of an organization committed to advancing research and improving outcomes. By working with dedicated colleagues, I advocate for patients and ensure they have access to innovative therapies that could change their lives."

"As a Patient Advocate, I collaborate to make clinical trials more accessible and fair, ensuring that all patients, regardless of language or background, have the chance to benefit from the latest cancer research."

Marlyn Molero

Clinical Research Associate, Mission Hope Cancer Center

CLINICAL TRIAL MANAGEMENT SYSTEM SHOWS EXCITING ENROLLMENT TRENDS

Now two full years into implementation, the Clinical Trial Management System (CTMS) allows the Research Institute to track all prospective trials, site activity and enrollment across the national footprint.

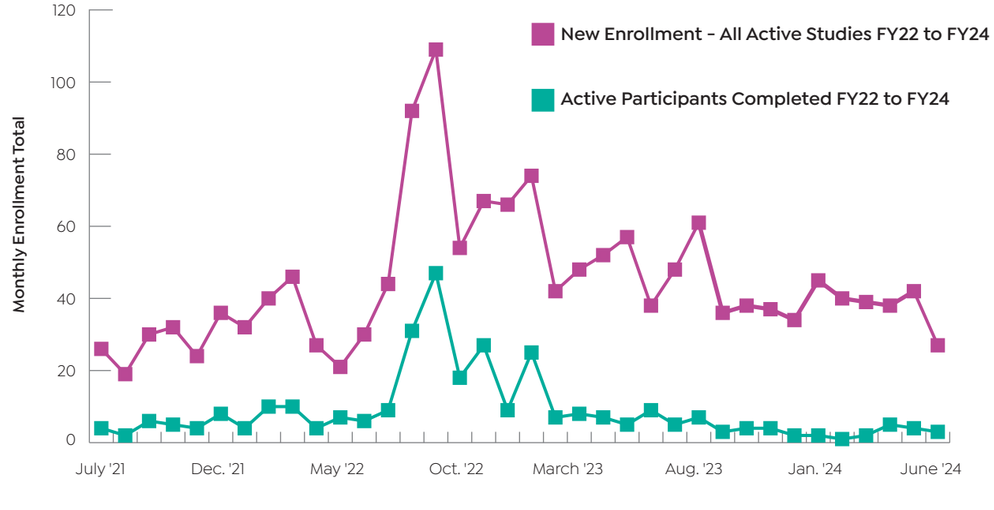
These charts show how enrollment spiked due to seven CommonSpirit sites enrolling 250 participants into the Freenome Vallania study beginning in FY22. CommonSpirit was also the number one enroller in Medtronic Alleviate HF study that also resulted in nearly 90 participants enrolled. Participants coming off trials also spiked as the Freenome participants only participated for a year where more traditional prospective trials have 2+ year treatment and longer term follow up cycles.

"As we only have two full years of tracking information on our CTMS platform, we started with many participants already enrolled during our data migration and likely already near the end of their participation and follow up," explains Mary Rydman, System Director Research Operations. "Going into FY25, we believe we'll see enrollment increase again as we continue to leverage our national footprint to open new multi-site industry funded trials like the Freenome Vallania study, focus on higher enrolling NCI trials and optimize our new study start up process, including assessing poorer performing studies for closure where they haven't enrolled any subjects in first 12 months of the study opening for enrollment."

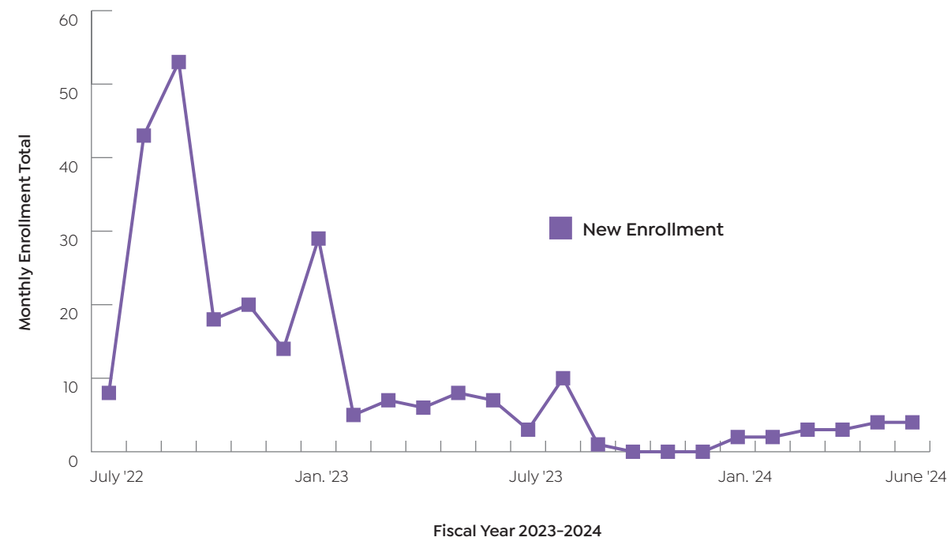
Mary Rydman
MPA, System Director
Research Operations

"Going into FY25, we believe we'll see enrollment increase again as we continue to leverage our national footprint to open new multi-site industry funded trials."

All Active Studies (FY22-FY24)



Freenome Trial (FY23-FY24)



Mountain Region

As was the case for many services within CommonSpirit Health, there was much work done within the Research Institute in FY24 to foster the integration of Centura Health.

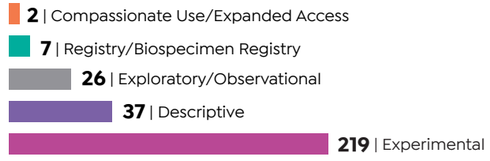
For the Mountain Region research team (formerly the Centura Research Operations team), the process of disaffiliating with Advent Health and affiliating with CommonSpirit was their primary focus during FY24. During this time, the team put a hold on initiating new studies in order to focus on the administrative work of alignment, while also continuing to manage active participants that were on-study.

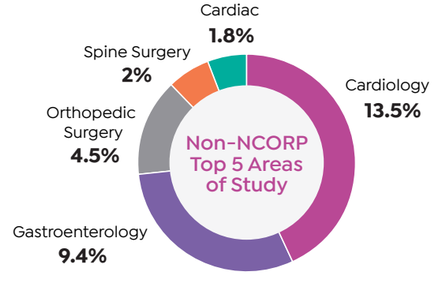
301
Open Studies

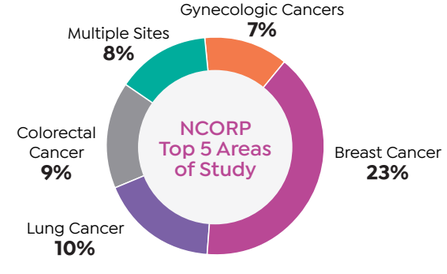
10
Open Humanitarian Use Devices

By aligning Centura's research team with the Research Institute, patients will benefit from access to a vast research study portfolio and investigators will benefit from the enhanced support and centralized budget and contract teams. In addition, the Mountain Region research staff looks forward to accessing the robust quality assurance and education programs available through the Research Institute, as well as opportunities to network with research professionals throughout the CommonSpirit ministry.

Active Projects by Protocol Category







BECOMING COMMONSPIRIT: EMBRACING THE DIFFICULT TASK OF ALIGNMENT

In the summer of 2023, Advent Health and Catholic Health Initiatives opted to disaffiliate. At this time decisions were also made to have the Catholic Health Initiatives component of Centura align with CommonSpirit Health to become the Mountain Region.

"The Centura Research Operations team had to quickly determine which studies would stay with Catholic Health Initiatives and which studies would be transferred to Advent Health," explains Jared Rowe, PharmD, Research Operations Director, Mountain Region. "Research participant safety was the number one primary focus of this transition work."

The Catholic Health Initiatives research staff spent a significant amount of time training the newly hired Advent Health research staff on both general and study-specific research procedures, including scheduling participant visits to introduce every active participant to the new Advent Health study team. There was also administrative work done notifying sponsors of the transition, revising contracts and budgets as well as IRB notifications. In the end there were more than 160 studies with 147 active participants transferred to the new Advent Health research team. This research disaffiliation work was formally completed in February 2024.

"Now that disaffiliation with Advent Health is complete and alignment with CommonSpirit is in progress, the Mountain Region research team looks forward to growing the research enterprise within the region."

Jared Rowe
PharmD, CIP, Director, Research Operations

California Region

Research in CommonSpirit Health's California Region continues to be robust, with sites scattered across the state, including the greater Sacramento area, Central Coast, Central California, Southern California, North State, and Bay Area.

Clinical areas of interest include cardiovascular, oncology, neurology, and infectious disease.

STRONG INFRASTRUCTURE SUPPORT ENABLES GOAL-BREAKING ENROLLMENT

The NIMBLE Study looks at a possible new medicine for people with eosinophilic asthma (a type of severe asthma). The study examines GlaxoSmithKline's GSK3511294, a monoclonal antibody that works by blocking a specific protein in the body (interleukin-5) which is involved in the severity of asthma and inflammation of the lungs. The NIMBLE study examines whether the study drug works at least as well as at treating severe asthma as mepolizumab or benralizumab.

The NIMBLE study had a total of 495 sites across the globe and Dignity Health Woodland Clinic site was the top enroller in northern California.

"Our enrollment goal was five screened, three randomized and our site's enrollment is now at eight screened, five randomized," says Principal Investigator Rajan K. Merchant, MD, FACAAI, Allergy, Asthma, and Clinical Immunology Specialist, Woodland Clinic Medical Group. "The northern California medical liaison visited our site and asked us for tips on how they could help other sites maximize enrollment efforts."

The team credits strong infrastructure and data support in helping achieve their remarkable enrollment rates.

"One of our greatest strengths as a site is having the capacity to run data reports, specific to the study's enrollment criteria, which allows us to prescreen clinic patients," says Jasdeep Shergill, MBS, ACRP-CP, Certified Clinical Research Coordinator. "Lucy Ng-Price, MA, CCRC, Senior Certified Clinical Research Coordinator, and I dedicate time and effort towards prescreening each individual chart in EMR, prior to scheduling a screening visit. This helps minimize the screen failure rate at our site."

Dr. Merchant points out that this type of thorough pre-screening helps to create a patient-centric focus that helps to convey that the patient is why we conduct research.

The burden of severe asthma is very high, with many patients on multiple daily medications and injections once or twice a month. Findings from the NIMBLE study will add to treatment options for severe asthma by focusing on decreasing the burden by providing a twice-yearly treatment for severe asthma, which could improve overall compliance and better health outcomes.

Rajan K. Merchant

MD, FACAAI, Allergy, Asthma, and Clinical Immunology Specialist

COMMUNITY OUTREACH AND PREVENTATIVE HEALTH CARE INITIATIVES: PROSTATE CANCER SCREENINGS

Thanks to collaboration with sponsor PCEC (Prostate Conditions Education Council), the Mercy Regional Cancer Center (Redding, California) is able to screen and educate dozens of community members during free Prostate Screening Events held annually in Sacramento, Redding and Woodland.

The event is a multi-specialty, collaborative partnership involving two urologists, four family practice resident physicians, six hospital phlebotomists, cancer registry staff, four hospital volunteers and the center's oncology director.

"Participants from previous years are contacted by our staff via phone or email weeks before the event to inform them of the scheduled date, time and venue," says Jo-Ann L. Medina, CCRP, Oncology Clinical Research Coordinator, Mercy Regional Cancer Center Redding. "We've held the event since 2016. There is camaraderie among the men as they see each other every year for this event. Patients keep track of their PSA lab results and digital rectal examination findings from previous years. They have increased awareness of clinical screening and early detection of abnormalities, if present."

The Cancer Center staff update the participants of their laboratory results by mail or phone and make the necessary urology referral for continuity of care.

Dr. Patrick Fowler, Mercy Regional Cancer Center urologist, appears on local news to promote the center's annual prostate screening and trial enrollment event.

2023 Prostate Cancer Screening and Trial Enrollment Event

72 men participated

60 consented to join trial

30% increase compared to 2022

SEQUOIA HOSPITAL LEADS THE WAY IN TRANSLATIONAL RESEARCH

Dignity Health Sequoia Hospital (Redwood City, California) is playing a pioneering role in cancer diagnosis through the Precision Biopsy program headed by Anobel Tamrazi, MD, PhD, vascular and interventional radiology specialist.

This program was initiated and established by Dr. Tamrazi in 2016 with funding coming from generous philanthropic support of the Sequoia Hospital Foundation by members of the community. Dr. Tamrazi and his team, consisting of nurse coordinators Juanita Fujii and Zayna Shaheen, program manager Srividya Sundaresan, and Sequoia clinical research managers Ann Campbell and Lucas Anderson, have developed the Precision Biopsy program at Sequoia into a hub of leading-edge translational research.

Their mission is to bring the benefits of the latest scientific breakthroughs to patients and enable comprehensive tumor analysis to select appropriate personalized targeted therapies for each patient. The team has initiated both internal projects and external collaborations with biotech start-ups. These projects are made possible by CommonSpirit institutional review board (IRB)-approved protocols that allow for patient-consented research studies, including long-term (up to 10 years) follow up of clinical outcomes.

Northwest Region

CommonSpirit Health Research Institute work in the Northwest Region is anchored by Benaroya Research Institute (BRI) in Seattle, with additional studies led by clinicians throughout Virginia Mason Franciscan Health.

ALLEVIATE HF STUDY: COMMONSPIRIT HEALTH NORTHWEST REGION TOP ENROLLER NATIONALLY

Researchers in CommonSpirit Health's Pacific Northwest region are the top enroller nationally in the Alleviate HF study, which studies the Medtronic Reveal LINQ, an insertable cardiac monitor to identify patients at high-risk of worsening heart failure.

David Zhang, MD

PhD, FACP, FACC, Cardiology, Virginia Mason Franciscan Health

The Reveal LINQ ICM can automatically detect and record abnormal heartbeats with smart technology, using an at-home bedside transmitter that shares monitoring information with the treating physician.

Alleviate HF evaluates use of the LINQ Heart Failure Risk Status algorithm to guide patient care in subjects with class II or III congestive heart failure.

The LINQ device will alert clinicians if a patient is at high risk for a heart failure event, allowing time for a physician to adjust medications to enhance patient health. The CommonSpirit team credits many factors for their success with the ALLEVIATE-HF study, beginning with the collaboration between the hospital and clinic teams. The team enrolled 75 patients into this important landmark heart failure trial.

"Because of the collaboration between our teams, we were able to identify the appropriate patients very early and immediately after a qualifying event occurred," says Dr. David Zhang, a Virginia Mason Franciscan Health heart failure cardiologist who is also PI of this study. "In addition, our investigators at all levels were engaged and demonstrated seamless team work at the system level."

PIONEERING EARLY SCREENING FOR AUTOIMMUNE DISEASES

One in seven Americans live with an autoimmune disease. While screening and early detection are widely available and encouraged for most other common conditions, screening for autoimmune diseases is very new and has not been widely done in doctors' offices.

Jane Buckner, MD

Rheumatologist and President, Benaroya Research Institute

The team at Benaroya Research Institute (BRI) is working to change that, implementing some of the first primary care-based screening for autoimmune diseases.

"This study is building on decades of advances at BRI and other institutions," says Jane Buckner, MD, Rheumatologist and President, Benaroya Research Institute. "We know that a person develops proteins called autoantibodies in their blood long before they develop symptoms of most autoimmune conditions. A simple blood test can detect these autoantibodies. Our question is how to integrate this test into primary care so it's as easy as possible for patients and providers to get information about autoimmune disease risk."

This type of screening can provide vital health information: If people know they are on track to develop an autoimmune disease like type 1 diabetes or rheumatoid arthritis, they can watch for early warning signs and help avoid a life-threatening complication like diabetic ketoacidosis.

"This study is also moving us one step closer to finding ways to prevent autoimmune diseases," Dr. Buckner says. "Through studies like this, our team at BRI is making progress towards our mission to advance the science to predict, prevent, reverse and cure diseases of the immune system."

USING PHILANTHROPY TO FUND INNOVATIVE AND VISIONARY RESEARCH

Benaroya Research Institute (BRI) recently launched an Innovation Fund to support visionary research and take science in new directions. The fund, powered by philanthropy, enables BRI scientists to test and implement new technologies through innovative research projects. After the initial project, the technology becomes available to scientists across BRI.

BRI's Caroline Stefani, PhD, and Eddie James, PhD, are leading one of the first studies the Innovation Fund is supporting, which looks at whether beta cells can be made more resilient in patients with type 1 diabetes (T1D).

Beta cells live in the pancreas and help our bodies make insulin. But in people who have T1D, beta cells get mistakenly attacked by immune cells called T cells.

"We think about it like giving the beta cells a bulletproof vest or a survival pack," Dr. Stefani says. "Even if the cells get attacked, can we make them more resilient so they can repair themselves or survive longer?"

Innovation funding will first help the team to build the infrastructure needed to grow human beta cells, a process James Lab postdoc Aisha Callebaut, PhD, learned from an expert group in Belgium and brought back to BRI.

With replenishable access to these cells, Dr. Stefani is developing methods to gather detailed information about what might make them weaker or stronger. This will enable their team to test whether gene changes or various medicines can make beta cells more resilient.

As with all the work powered by the Innovation Fund, the study will likely yield results that can be applied in a variety of ways, having a ripple effect across labs and disease areas at BRI.

"My hope is that we can give more of these grants out each year and grow our capabilities even more," Dr. James says. "We're so excited to see this fund up and running and so grateful for everyone who supports it."

Caroline Stefani, PhD
Research Assistant Member, Benaroya Research Institute

Eddie James, PhD
Associate Member, Benaroya Research Institute

MARKET RESEARCH MANAGER LEADS WITH PRECISION AND PURPOSE

As Market Research Manager in CommonSpirit Health's Northwest Region, Dalia Sherif has carved a niche for herself as a leader who combines deep technical knowledge with a sharp focus on building collaborative teams.

Dalia's path began in the bustling streets of Cairo, where she earned her medical degree and later a master's degree in Clinical and Chemical Pathology. Her medical education provided a strong foundation that she would later bring to the world of clinical research. With over a decade of hands-on experience in clinical trials — both industry-sponsored and investigator-initiated — Dalia has honed a unique skill set, blending scientific rigor with practical execution.

Her global perspective, having worked across the Middle East and Washington State, has equipped her to navigate the complexities of cross-cultural work environments with ease. Today, Dalia continues to innovate. Her commitment to quality assurance and efficiency is unwavering. She ensures her teams adhere to Good Clinical Practice (GCP) guidelines, maintains strict timelines, and enforces data integrity standards across all trials.

Dalia Sherif
MBBCh, MS, ACRP-CP

BENAROYA RESEARCH INSTITUTE PRESIDENT HONORED FOR HUMAN IMMUNOLOGY RESEARCH

In recognition of her pioneering work advancing the science to diagnose and treat autoimmune disease, Jane Buckner, MD, president of Benaroya Research Institute, received the prestigious 2024 American Association of Immunologists' Steinman Award for Human Immunology Research.

Specifically, Dr. Buckner was honored for her substantial contributions to defining and characterizing the genetic basis of human autoimmunity. Dr. Buckner's current research focuses on engineered regulatory T cells, a groundbreaking new approach that uses a person's own cells to treat autoimmune diseases. Most autoimmune disease treatments slow down the entire immune system, leaving a person vulnerable to infections. This approach holds the promise of a highly-targeted treatment aimed at the root cause of disease — and could potentially open the door to cures.

Central Region

CommonSpirit Health Research Institute work in the Central Region is anchored in work done at Barrow Neurological Institute at Dignity Health St. Joseph's Hospital and Medical Center (Phoenix, Arizona) and Creighton University School of Medicine (Nebraska), with additional studies led by clinicians throughout the region.

BEHAVIORAL HEALTH RESEARCH TAKES CENTER STAGE IN NEBRASKA

Under the leadership of Molly Davis, MS, Market Manager of Research at CHI Health Research Center, researchers in Nebraska have made significant strides in addressing the growing need for comprehensive mental health care, prioritizing studies that focus on innovative treatments for anxiety, depression, and substance use disorders.

In 2024, Nebraska-based researchers in the Central Region successfully participated in three major industry-sponsored trials, exploring groundbreaking therapies and interventions. These trials not only support the local community but also position CHI Health as a leading contributor to behavioral health research. The team is actively seeking to expand its portfolio by adding more trials that push the boundaries of behavioral health care and improve patient outcomes.

Molly Davis and her team have worked tirelessly to foster collaborations with local health care providers and academic institutions, ensuring that the research being conducted has a direct, positive impact on patients. By combining community outreach with cutting-edge clinical trials, the Central Region is creating pathways to better, more accessible behavioral health care for all.

HEART: REACHING THE UNDERSERVED AND UNDERSTUDIED

Hispanics affected by Alzheimer's disease constitute an underserved and understudied population in the United States. Through its Hispanic Enrollment in Alzheimer's Research Trials (HEART) program, Barrow Neurological Institute (Phoenix, Arizona) partners with various organizations in the community to help address the educational and clinical needs of patients and families and to demonstrate to this underserved community

Anna D. Burke, MD

Karsten Solheim Chair for Dementia, Barrow Neurological Institute

Under the direction of Marwan Sabbagh, MD, and Anna Burke, MD, HEART serves to further not only the ability to treat Alzheimer's disease through early diagnosis, but also the ability to address health equity issues in a historically underserved community.

Through both internal and external outreach, the HEART program engages with the Hispanic community and increases recruitment and retention of Hispanic subjects in the Arizona Alzheimer's Disease Core Center and other research protocols by removing unique cultural barriers and increasing awareness and access to resources.

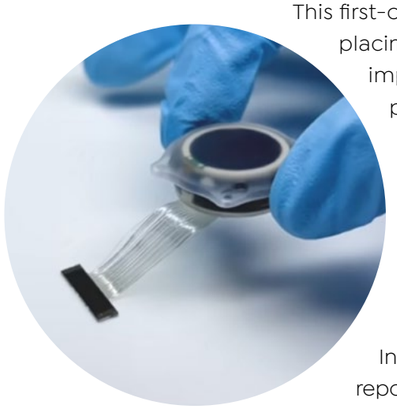
"By collaborating with other health care providers in our region, and with the support of state funding, we are able to reach and serve one of our largest but historically most underserved communities," explains Anna D. Burke, MD, Karsten Solheim Chair for Dementia, Barrow Neurological Institute.

BNI recognized more than 200% growth in outpatient clinic volume from 2016 to 2018, and Hispanics contribute to more than 38% of the total patient population. The culturally dense population seeking care at BNI presents a unique opportunity to address awareness and increase participation in Alzheimer research trial opportunities within Arizona.

RESEARCHING HOPE FOR SPINAL CORD INJURIES

Researchers at Barrow Neurological Institute are playing a pivotal role in developing hope for people living with debilitating spinal cord injury. Approximately 18,000 people have spinal cord injuries (SCI) each year in the United States; resulting in an estimated 302,000 people living with SCI from a traumatic event.

The PRIME Study is an investigational medical device trial for Neuralink's fully implantable, wireless brain-computer interface (BCI). The study evaluates the safety of the implant and surgical robot and assesses the initial functionality of the BCI for enabling people with quadriplegia to control external devices with their thoughts.



This first-of-its-kind study involves placing a small, cosmetically invisible implant in a part of the brain that plans movements. The device is designed to interpret a person's neural activity, so they can operate a computer or smartphone by simply intending to move – no wires or physical movement are required.

In April 2024, Barrow researchers reported that the first participant in Neuralink's PRIME Study demonstrated the ability to use brain activity to command an external device in a successful procedure at Barrow.

Francisco Ponce, MD, Chief of Stereotactic and Functional Neurosurgery at Barrow Neurological Institute and one of the investigators for the PRIME Study, said, "Barrow is dedicated to improving the quality of life of our patients, and we are proud to be part of this novel research that leverages medical and computer technology to potentially and profoundly impact the lives of people living with a disability."

Barrow was selected as the inaugural site for the Neuralink PRIME Study based on its expertise in caring for patients with the most complex of neurological conditions.

We remain hopeful that a BCI device may enable a digital bridge between the brain and spinal cord to potentially improve the quality of life for people with severe spinal cord injuries.

Rory Murphy, MD

Neurosurgeon and associate professor in the Department of Neurosurgery at Barrow Neurological Institute and an investigator at Barrow for the PRIME Study

$51M+
in Federal Funding Received as Prime Recipient**

**FY2021

345
Active Clinical Trials

1,200+
Patients Currently Enrolled in Clinical Trials

42
Current Academic Collaborations

8 Current Federal Funding Agencies

196
Peer-Reviewed Articles Published*

*FY2023

USING RESEARCH TO FIND ANSWERS FOR EXPOSED WORKERS ON THE OTHER SIDE OF THE WORLD

As demand for electric vehicles has soared in recent years, automakers have rapidly turned to manganese, a common and relatively inexpensive mineral that is already used in about half of rechargeable batteries and is seen as key to making supply chains more reliable and cars more affordable. The industry's demand for manganese has quintupled over the past five years and is expected to continue to grow exponentially.

Unfortunately, we are now learning that exposure to high levels of manganese can be toxic, leading to a wide spectrum of neurological damage.

Neurologist Brad Racette, MD, chair of neurology at the Barrow Neurological Institute, examined 187 manganese miners and found that a quarter of these miners experienced Parkinsonian symptoms, such as abnormally stiff and slow movement. His team, which conducted the study between 2010 and 2014, also found that these symptoms were associated with a lower quality of life, as reported by the workers in surveys.

"We are still peeling the layers off this onion," Dr. Racette told the Washington Post in a June 2024 article. "My question at this point is how low the [exposure] levels need to go before they are safe."

South Region

Research in CommonSpirit Health's South Region includes work in Arkansas, Georgia, Kentucky, Tennessee, Texas, and Ohio.

In Texas, research is led by the Texas Division Research Review Council, a team formed to support and guide all research endeavors in the state not managed by Baylor College of Medicine.

RESEARCH TYPE

Student/Mentorship, Data, HUD: **34%**

Pending Startup: **6%**

Active Studies: **26%**

Withdrawn/Canceled: **19%**

Completed, Closed, Prepping for Closeout: **15%**

TEXAS RESEARCH SITES

Baylor St. Luke's Medical Center — Houston

- Texas Heart Institute
- UTHealth
- Kelsey-Seybold Clinic

St. Joseph Health Regional Hospital — Bryan, Texas

- Texas A&M University

TEXAS AREAS OF STUDY

Cardiovascular: 15

Oncology: 6

IRB-APPROVED FOR HUMANITARIAN USE DEVICE ONLY

St. Luke's Health

- Brazosport Hospital (Lake Jackson, Texas)
- Sugar Land Hospital (Sugar Land, Texas)

POTENTIAL ACTIVE RESEARCH SITES IN THE FUTURE

St. Joseph Health
College Station Hospital (pending startup)

St. Luke's Health

- The Woodlands Hospital (pending approval)
- The Vintage Hospital

TEXAS RESEARCH REVIEW COUNCIL UNITES RESEARCH THROUGHOUT SOUTHEAST TEXAS

In FY24, the CommonSpirit Health Texas Research Review Council accelerated its work promoting research across Texas by ensuring projects have scientific and strategic merit, are well-resourced, comply with regulatory guidelines, and involve properly trained researchers.

Huma Javaid

MS, CCRP, Market Research Manager (Southeast Texas/Brazos Valley)

"One of the key objectives of the Council is to improve oversight for research conducted at CommonSpirit Health research facilities throughout southeast Texas," explains Huma Javaid, MS, CCRP, Market Research Manager (Southeast Texas/Brazos Valley). "Previously, research often occurred without leadership awareness or proper approvals. Now, nearly all new research projects must be presented to the Council for review and approval."

The Council provides acknowledgment letters to investigators after reviewing new research proposals, enhancing transparency and communication. The Council provides data request management, streamlining and filtering data requests by creating a detailed intake form and collaborating with the clinical analytics team to review the data.

In addition, the Council has successfully advocated for a master data use agreement with Baylor College of Medicine. The Council is currently working to enlist a leadership re-review of the existing affiliation agreement to facilitate research for Baylor investigators outside Baylor St. Luke's Medical Center.

KENTUCKY MARKET WORKS TO FIND NEW OPTIONS FOR MS TREATMENT

The CommonSpirit Health Research Institute team in Kentucky is engaged in the ENABLE trial (rEal world experieNce with BRIUMVI® [ublituximAB-xiiy] treated patients: a Longitudinal rEgistry study).

The study aims to collect demographics and medical history for patients initiating BRIUMVI® (ublituximAB-xiiy), an immunosuppressant monoclonal antibody for people with relapsing multiple sclerosis (RMS). The medication works by targeting CD20, a protein found on the surface of B cells and induces B-cell depletion within 24 hours. B cells are white blood cells shown to play a role in MS.

The CommonSpirit research team is collecting real world data on the effectiveness of the drug, including the incidence of relapse, as well as the safety and tolerability (including the infusion experience). They are also assessing laboratory values as part of patients' routine clinical care.

Market Highlights

CORA recognized the Kentucky market as the third highest accruing market and most improved site for data timeliness and query response.

In June 2024, Freenome closed enrollment to the Vallenia trial. Kentucky's enrollment ended with 180 participants enrolled.

Cardiovascular

CommonSpirit Health's cardiovascular service line is focused on participating in and leading transformative clinical trials by capitalizing on existing data assets, such as the STS/ACC TVT Registry™ for real world evidence and programmatic research. By harnessing Signal Path, participant Intelligence and REDCap tools, our research leads have the ability to make more informed decisions and accelerate progress toward meeting our collective goal of transforming care.

TOP 5 THERAPEUTIC AREAS

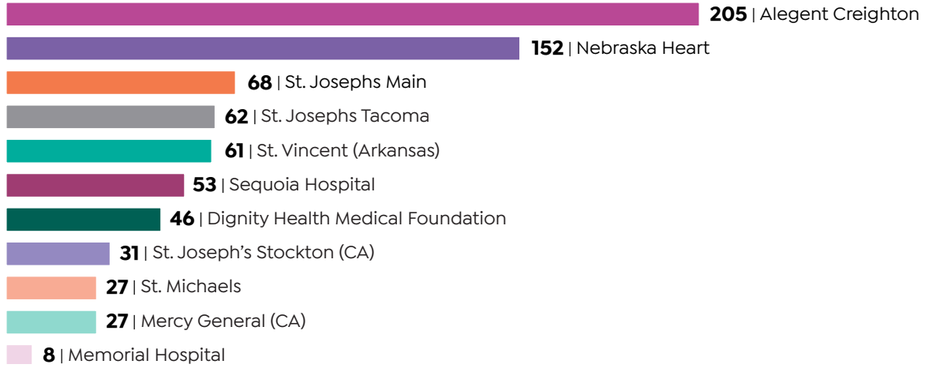
Atrial Fibrillation: **14**
Congestive Heart Failure: **8**
Coronary Atrial Disease: **5**
Arrhythmia: **5**
Stroke: **3**

Study Highlights

Active Protocols: **66**

Unique Protocols: **59**	Interventional Studies: **83%**	Observational Studies: **17%**
Total Patients Enrolled: **740**	Active Participants: **674**	Patients on Active Treatment: **66**

Enrollment by Sites



TAVR REGISTRY: HARNESSING THE BREADTH OF OUR MINISTRY FOR THE GOOD OF ALL PATIENTS

CommonSpirit Health facilities currently perform as many as 3,000 TAVR (Transcatheter Aortic Valve Replacement) procedures annually, accounting for a significant portion of all TAVR procedures in the U.S.

Now, CommonSpirit has secured IRB approval to maintain a TAVR database, a vital tool that will help inform providers about the real-life experiences of the patients receiving this groundbreaking treatment.

"The TAVR registry is a research initiative that attempts to utilize the CommonSpirit experience to address epidemiologic questions and observational research questions related to this procedure," says Nezar Falluji, MD, MPH, MBA, FACC, FSCAI, System Physician Vice President, Cardiovascular Service Line. "Through the observations of the registry, we hope to investigate and explore trends that may develop in this patient population and address the questions that have not yet been answered."

Dr. Falluji believes harnessing the information available in the vast breadth of outcomes throughout the CommonSpirit footprint is one of the benefits of our unified, collaborative ministry.

"This is the perfect example of One CommonSpirit," he says. "We are bringing together the entire CommonSpirit collective experience for the good of all our patients."

Nezar Falluji, MD
MPH, MBA, FACC, FSCAI,
System Physician Vice President,
Cardiovascular Service Line

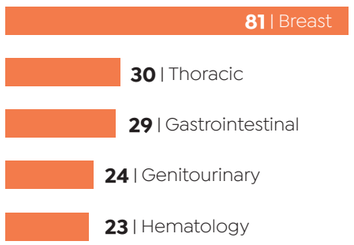
Oncology

The CommonSpirit Research Institute oncology research network includes 29 sites across seven states that are actively enrolling in National Cancer Institute (NCI), industry- and other grant-funded studies, with nearly 1,300 total participants enrolled.

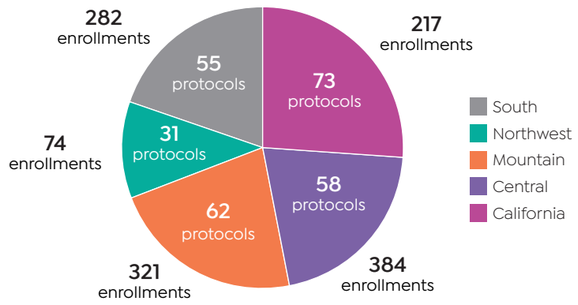
This national endeavor is supported by **30** principal investigators and **33** full-time employees across all sites. These trials are interventional, observational and participant registries.

279 Active Protocols (All Sites)	**260** NCI Protocols	**127** Unique Protocols	**89%** Interventional Studies
11% Observational Studies	**1,897** Total Participants (Active and Inactive)	**1,278** Total Active Enrolled Participants	**384** Patients on Active Treatment

Top Five Therapeutic Areas

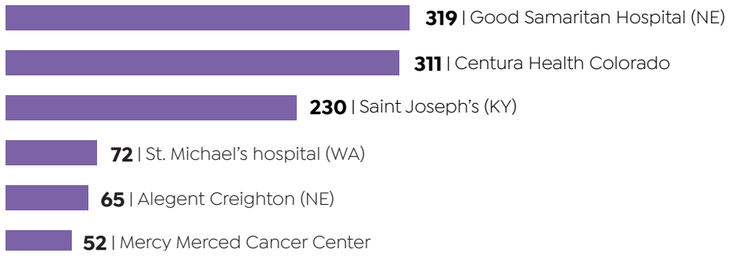


Active Protocols and Enrollments by Region



Phase II: **31** Phase II/III: **25** Phase III: **154** Phase IV: **10**

Total Enrollments by Sites



Advancing Patient Care Through NCORP Opportunities

CHANGING THE WAY CANCER IS TREATED

At CommonSpirit Health, a cornerstone of our oncology research is the development of innovative treatment protocols that not only improve clinical outcomes but also enhance the quality of life for our patients. Under the leadership of Dr. Samer Shihabi at the Dignity Health Medical Foundation Mercy Cancer Center in Sacramento, our team is actively contributing to this mission through our participation in the CompassHER2-pCR, a cooperative group trial available through CSHRI's NCORP (CORA).

This pivotal phase II trial focuses on evaluating the efficacy of combining paclitaxel, trastuzumab, and pertuzumab for patients with HER2-positive stage II-IIIa breast cancer. The goal is to potentially eliminate the need for further chemotherapy post-surgery in those who show no residual cancer in the breast or underarm lymph nodes following pre-operative chemotherapy and HER2-targeted therapy. Paclitaxel operates through various mechanisms to stop tumor growth, including cell death, division inhibition, or metastasis prevention. Trastuzumab specifically targets and attaches to HER2 receptors on tumor cells, blocking essential growth signals and marking the cells for immune destruction. Meanwhile, pertuzumab enhances this effect by disrupting tumor cell growth and spread.

"By administering paclitaxel, trastuzumab, and pertuzumab, we aim to reduce our reliance on traditional chemotherapy drugs, maintaining high-quality patient outcomes," Dr. Shihabi says. "It's rewarding to provide our patients with innovative treatments that could significantly reduce their treatment burden."

This integrated approach underscores our dedication to leading-edge cancer care, focusing on treatments that are not only effective in combating the disease but also in safeguarding our patients' overall well-being.

Samir Shihabi, MD

Hematologist/Oncologist, Dignity Health Medical Foundation Mercy Cancer Center

Advancing Patient Care Through NCORP Opportunities

CLINICAL RESEARCH OPPORTUNITIES FLOURISH THROUGH NCORP

For five years, oncology research at CommonSpirit Health Research Institute has been firmly anchored by NCORP, a National Institutes of Health grant operated through the National Cancer Institute. Initially awarded at $1.1 million per year for five years, CommonSpirit has been awarded more than $6 million in funding during this time. In addition, CommonSpirit's grant has been extended through July 2026, ensuring continued opportunities for our patients nationwide.

Mital Patel, MD, Gastrointestinal Medical Oncologist at Dignity Health Cancer Institute at St. Joseph's Hospital and Medical Center (Phoenix, Arizona) has witness firsthand the dramatic effect NCORP opportunities can have.

"Prior to NCORP, our team of 15-18 physicians were limited in the trials we could open," Dr. Patel explains. "Now, through NCORP, we have access to a very comprehensive portfolio, including national and international trials."

Dr. Patel and the team at St. Joseph's have seen their accrual increase steadily. "In the past we had maybe 40 to 50 total each year," he says. "Now, we are six months into the year and we are at 40 to 45."

In the past, Dr. Patel's patients would have had access to three or four GI trials; now, it is not uncommon to have 15 to 20 NCORP trial options.

"As an academically oriented site, we have residency programs, teaching programs, etc., and the goal is always to bring clinical trial enrollment to the forefront of options for our patients," he says. "Now we can offer a variety of options to address each patient's unique needs."

Mital Patel, MD

Gastrointestinal Medical Oncologist, Dignity Health Cancer Institute, St. Joseph's Hospital and Medical Center

BREADTH AND VARIETY OF NCORP TRIALS PUSH ADVANCEMENTS

"The JANUS (A022104) trial is moving the needle on neoadjuvant therapy of rectal cancer and providing the patients the option of organ preservation. The DIRECT (EA1211) trial provides our breast cancer patients with additional imaging to determine its value in prediction of early responses to their chemotherapies. The Raptor (NRG-LU007) trial is examining the improvement in survival of patients with small cell lung cancer by using a combination of radiation and immunotherapy once done with their chemotherapy. Overall, the spectrum of trials are asking critical questions in oncology with respect to response prediction, improving patient survival and also challenging historic treatment protocols."

— Mital Patel, MD, Gastrointestinal Medical Oncologist at Dignity Health Cancer Institute at St. Joseph's Hospital and Medical Center

CommonSpirit NCORP 2024 Study Portfolio

6 CNS	**19** Breast Cancer	**6** Gynecologic	**4** Head and Neck Cancer
15 Lung Cancer	**7** Hematology	**16** GI	**18** GU
1 Endocrine/ Neuroendocrine	**15** Other*	**2** Melanoma	**1** Sarcoma

*multiple cancer types, metastatic disease, screening/prevention studies

Active (Open to Enrollment) 77

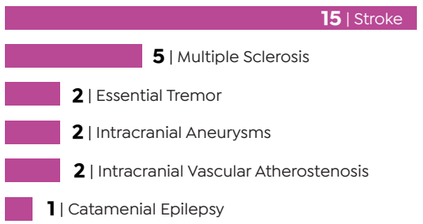
Just in Time 33

Active (Not Recruiting/ Maintenance) 137

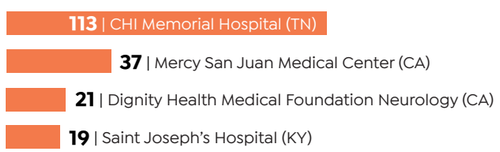
Neurology

CommonSpirit Health's neuroscience research teams engage in multi-center, national, and international clinical research trials, driving innovation in neurology and stroke care. Their active participation in these trials contributes to the exploration of novel preventive measures and leading-edge treatments across a spectrum of neurological conditions, including stroke, Alzheimer's and dementia disorders, aneurysm, multiple sclerosis, epilepsy, and headache disorders.

Top 5 Therapeutic Areas



Top Enrollments by Site



Observational Studies

Interventional Studies

COMMONSPIRIT LEADS RESEARCH ON GROUNDBREAKING STROKE DRUG

Backed by a history of leading the industry in stroke research, earlier this year CHI Memorial Hospital (Tennessee), in collaboration with Lumosa Therapeutics, announced the initiation of multiple Phase 2 clinical trials for LT3001. The drug extends the critical treatment time window for stroke to 24 hours, compared to four and a half hours currently for intravenous t-PA.

"This could very well end up being the most important study in the history of stroke, if approved," says Thomas Devlin, MD, CHI Memorial Neuroscience Institute Medical Director and the national principal investigator on the trial. "We believe this drug may redefine what is possible in preventing stroke disability and impairment."

LT3001 can be administered within 24 hours after stroke onset for smaller, medium, or larger strokes, in both large and smaller rural hospital emergency departments, potentially expanding patient access to acute stroke therapy. It works by breaking down clots while also providing neuroprotective effects that offer hope for significantly improved outcomes.

CHI Memorial serves as the coordinating center for all Lumosa stroke studies in the U.S. Dr. Devlin is the international principal investigator for the Lumosa 203 and BRIGHT studies, both of which are Phase 2, randomized, placebo-controlled, double-blinded trials. The 203 study focuses on patients undergoing mechanical thrombectomy, while the BRIGHT trial studies those not undergoing thrombectomy.

Both trials are expected to be completed within the next year or so.

Thomas Devlin, MD, PhD

CHI Memorial Neuroscience Institute Medical Director

USING AI TO SUPPORT EARLY DIAGNOSIS OF ALZHEIMER'S DISEASE

Neurologists from two vastly different regions within CommonSpirit Health are collaborating to address one of the most challenging aspects of treatment for Alzheimer's disease: How to diagnose more people living with Alzheimer's disease in the early stages, when a new generation of medications can truly help them.

"These drugs are revolutionary," says Anna D. Burke, MD, Karsten Solheim Chair for Dementia, Barrow Neurological Institute (Arizona). "The problem is they are only effective in the early stages of the disease. Once we get past a certain point in the disease progression, that valuable window is lost."

Anna D. Burke, MD

Karsten Solheim Chair for Dementia, Barrow Neurological Institute

The medications in question are monoclonal antibodies, which have been shown to reduce plaque in the brain and reduce the rate of the progression of the disease.

Now, Dr. Burke is partnering with her neuroscience colleagues at CHI Memorial Stroke and Neuroscience Center (Tennessee) to participate in Project Pegasus, a study that will assess whether AI technology administered in the primary care setting would be helpful in supporting primary care physicians in making Alzheimer's diagnoses earlier.

"We've seen that often primary care physicians don't feel comfortable diagnosing Alzheimer's in the early stages," Dr. Burke says. "By using AI, we are trying to make it easy for the primary care physician. An algorithm will evaluate a digital cognitive assessment and will flag a potential case, and determine what kind of testing, labs and imaging may be needed, as well as potential safety issues like problematic medications."

The project is testing the technology in two settings: an urban setting in the Barrow Community Clinic at St. Joseph Medical Center in Phoenix, and in a rural setting – the CHI Memorial Community Clinic in Chattanooga, Tennessee.

"This project is made possible by some major funders, including the Global Alzheimer's Platform Foundation and the Davos Alzheimer's Collaborative," Dr. Burke says. "But it is also possible because of the work of the CHI Memorial Foundation and the Barrows team and our respective teams."

PARTNERSHIP PRODUCES MILESTONE TECHNOLOGY IN STROKE DIAGNOSIS

CHI Memorial Stroke and Neuroscience Center (Tennessee) has played an instrumental role in developing and studying the technology behind a new robotic transcranial doppler (TCD) ultrasound device created by industry partner NovaSignal.

Ruchir Shah, MD, CHI Memorial Medical Director of Stroke Program, is the QI and lead principal investigator for BUBL, the national research trial studying the TCD.

BUBL found TCD to be three times as effective as conventional testing in identifying cardiac abnormalities capable of producing blood clots that cause stroke, particularly patent foramen ovale (PFO) – or a hole in the heart. PFO is present in more than 40% of cryptogenic stroke patients.

By understanding the underlying cause of a stroke, neurologists will be empowered to deliver therapy that is far more effective at preventing another stroke.

"These results represent a milestone in stroke medical care," says Dr. Shah. "We anticipate this to be a new standard of medical care that will save many lives by preventing future strokes."

Ruchir Shah, MD

CHI Memorial Medical Director of Stroke Program

Congratulations to the CHI Memorial team on cultivating a research partnership that led to the development of a novel technology that will have a significant impact at reducing secondary strokes and will benefit patients both within CommonSpirit Health and beyond.

Innovate

Innovative partnerships are at the core of the work being conducted by Commonspirit Health Research Institute teams nationwide across the CommonSpirit ministry. These partnerships include robust relationships with industry leaders, clinical colleagues, academic institutions, and more. Each of these partnerships have a shared goal of improving care delivery and health outcomes. In addition, many also strive to address health inequities..

PCORI: PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

PARTNERING TO BUILD CAPACITY AND INFRASTRUCTURE

Leadership and staff of CommonSpirit Health Research Institute and Physician Enterprise serve as principal investigators for the Capacity Building Project, in partnership with PCORI (Patient-Centered Outcomes Research Institute).

The project needs relate to the specific implementation challenges arising from CommonSpirit's scale, the competing priorities that can stall change initiatives and siloed approaches that can result when rapidly evolving factors prompt reactive rather than proactive decision making.

The four prongs of the Capacity Building Project will support infrastructure needs related to data, analytics, program management, and HSII implementation.

- **Data Infrastructure**
- **Analytic Infrastructure**
- **Project Management Infrastructure**
- **Implementation**

These activities, spearheaded by the Research Institute, Physician Enterprise and the Research Analytics Center of Excellence, will bolster capacity to accurately collect, store and analyze data across CommonSpirit's 21-state footprint and successfully implement system-wide projects. The activities being undertaken capitalize on CommonSpirit's strengths while addressing gaps and creating systems that will drive the uptake of PCORI-funded research and best practices across the enterprise.

PARTNERING TO ENHANCE CARE FOR CHRONIC CARDIOVASCULAR DISEASE

Early in 2024 CommonSpirit Health announced a research partnership with Premier, Inc.'s PINC AI™ Applied Sciences (PAS) team aimed at gathering clinical and operational insights for a variety of disease states — including cardiovascular, neurological and acute and chronic conditions — to address the social causes of poor health and advance medical care delivery across the system's footprint.

With a shared emphasis on increasing health equity, the partnership combines CommonSpirit's national footprint, talent and research infrastructure with PAS' expertise in research development, to build healthier communities by addressing disparities in research, paving the way for rapid advancements in achieving more equitable health outcomes.

Neurologic and cardiovascular disorders disproportionately affect underserved groups, including racial and ethnic minorities, rural and socioeconomically disadvantaged populations.

Vani Nilakantan, Ph.D.

System Vice President Research, CommonSpirit Health Research Institute

"This collaboration is significant, enabling the teams to combine robust real-world data and artificial intelligence-driven research capabilities with a common passion for addressing the social causes of poor health and advancing health justice," said Vani Nilakantan, Ph.D., System Vice President Research, CommonSpirit Health Research Institute. "We're excited to conduct game-changing clinical research with PAS that we believe will accelerate improvements in health equity and care delivery in the U.S."

Key findings of one study conclude that more than 14 neurologic disease areas are affected by health disparities.

ACADEMIC PARTNER

Baylor College of Medicine

Located at the heart of the Texas Medical Center, the largest medical complex in the world, Baylor College of Medicine strives to improve health through science, scholarship and innovation. This vision is realized through collaborative research initiatives in which basic, translational, and clinical researchers work together across disciplines and specialties to discover fundamental insights into human health and disease and to apply their discoveries to develop new diagnostic tools and treatments.

In FY24, CommonSpirit Health and Baylor College of Medicine established a master data use agreement, allowing the two entities to partner closely through a data use committee, prioritizing resources and improving collaboration.

Departments Ranked in the Top 30 in NIH Funding

- **#1** Department of Molecular and Human Genetics
- **#2** Department of Pediatrics
- **#4** Department of Neuroscience
- **#4** Department of Molecular and Cellular Biology
- **#9** Department of Neurosurgery
- **#22** Department of Ophthalmology
- **#24** Michael E. DeBakey Department of Surgery
- **#27** Margaret M. and Albert B. Alkek Department of Medicine
- **#27** Department of Integrative Physiology
- **#28** Department of Pathology and Immunology
- **#29** Department of Radiology

National Institutes of Health Funding

NIH Funding FY23: $420 million+

Baylor's Rank Among U.S. Medical Schools in Direct NIH Funding FY23: #20

Rank Among Texas Medical Schools in Direct NIH Funding FY23: #1

OUTSTANDING RESEARCH CONTRIBUTIONS RECOGNIZED WITH DEBAKEY AWARDS

Baylor College of Medicine honored exceptional contributions to clinical and basic science research with the 2024 Michael E. DeBakey Excellence in Research Awards, given to six faculty members in recognition of their work over the past three years.

The recipients of the awards were Dr. Bing Zhang, Dr. Leonid Metelitsa, Dr. Maksim Mamonkin, Dr. Robert Atmar, Dr. Jeffrey C. Magee and Dr. Christine Beeton.

- Dr. Bing Zhang, Professor of Molecular and Human Genetics, has significantly advanced our understanding of cancer biology, improved data analysis methodologies and broadened data accessibility resources for the scientific community.
- Dr. Leonid Metelitsa, Professor of Pediatric Hematology and Oncology, is an internationally recognized leader in the field of natural killer T cell (NKTs) research, for bringing research bench to bedside, and as a leading expert in pediatric cancer immunotherapy.
- Dr. Maksim Mamonkin, Associate Professor in Department of Pathology & Immunology and the Center for Cell and Gene Therapy, is a translational immunologist engineering cellular therapies for hematologic malignancies and other diseases.

Honorees Dr. Christine Beeton, Dr. Robert Atmar, Dr. Maksim Mamonkin, Dr. Bing Zhang and Dr. Leonid Metelitsa with Dr. Carolyn Smith, interim SVP/Dean of Research at Baylor College of Medicine

FINDING INSIGHT INTO A DEBILITATING CHILDHOOD DISEASE

Researchers at Baylor College of Medicine and collaborating institutions have uncovered the molecular events leading to osteogenesis imperfecta type V, a form of brittle bone disease caused by a mutation in the gene IFITM5. The mutation blocks the normal development of bone stem cells and instead leads to the formation of bones that are extremely brittle.

Brendan Lee, MD

PhD, Chair, Molecular and Human Genetics

Children with this disorder have recurrent fractures, bone deformities, chronic pain and other complications.

"Brittle bone diseases, also known as osteogenesis imperfecta (OI), affect the connective tissue – tissues like bones, which support and protect other tissues in the body," said Dr. Brendan Lee, professor, chair and Robert and Janice McNair Endowed Chair of molecular and human genetics at Baylor. "Most types of OIs are caused by gene mutations that disrupt collagen synthesis or processing, but not OI type V."

The research team discovered that the IFITM5 mutation acts at the level of bone stem cells, altering the normal process that leads to bone formation; instead of progressing from cartilage to bone, progenitor cells form overgrown cartilage calluses where new bone should be. This finding helps to explain why patients with OI type V not only have bones that break easily, but when stem cells attempt to heal them, they form large calluses of cartilage instead of bone.

Until now, researchers had considered OI to be the result of abnormal bone development. Now they see that OI type V is the result of abnormal differentiation of a common stem cell.

This study is another example of the value of rare disease studies to improve the understanding and treatment of common diseases.

"Understanding how OI type V happens provides new insight into similar but more common skeletal conditions, such as osteoporosis, and also could result in improved treatments," Dr. Lee said.

ACADEMIC PARTNER

Creighton University School of Medicine

Creighton University School of Medicine strives to create a culture of inquiry, to improve health by asking relevant research questions and pursuing those answers. Research mentors are available in many fields of research in the School of Medicine. Within the Department of Clinical Research and Public Health, the Clinical Research Office has resources for all clinical research needs related to faculty- and student-led research from start to finish.

CREIGHTON UNIVERSITY SCHOOL OF MEDICINE/ CHI RESEARCH

(January 1 – July 1, 2024)

- Manuscripts or Abstracts Completed: **79**
- Accepted for Publication or Presentation: **24**
- Submitted, Awaiting Decision: **28**
- Research Projects Going to Completion: **75%+**
- Projected 2024 Submitted Manuscripts or Abstracts: **150**

SEEKING WAYS TO SUPPORT AND GROW RESEARCH EFFORTS

"Creighton University School of Medicine research leadership took steps in FY24 to bolster mentorship, increase collaboration and deepen the commitment to advancement of clinical research. Among the initiatives undertaken are expanded research interest groups, the development of investigator bootcamps, and the creation of an educational research roadshow."

Maureen R. Tierney

MD, MS, Associate Dean, Clinical Research and Public Health Chair and Professor

FISCAL YEAR 24 RESEARCH HIGHLIGHTS

Research highlights from Creighton University School of Medicine team members include:

- **Michael Koren, MD:** *Safety and immunogenicity of a purified inactivated Zika virus vaccine candidate in adults primed with a Japanese encephalitis virus or yellow fever virus vaccine in the USA: a phase 1, randomized, double-blind, placebo-controlled clinical trial.*
- **Michael Kim, MD, MMM:** *Role of connexin 43 phosphorylation on serine-368 by PKC in cardiac function and disease*
- **Himanshu Agarwal, MD:** *Transcatheter Aortic Valve Replacement With Self-Expanding Acurate Neo2 Valve Versus Acurate Neo Valve: A Meta-Analysis*
- **Mohammed Akhter, PhD:** *Bone Intrinsic Material and Compositional Properties in Postmenopausal Women Diagnosed with Long-Term Type-1 Diabetes*
- **Manasa Velagapudi, MBBS:** *Discharge Disposition and Clinical Outcomes of Patients Hospitalized with COVID-19*
- **Robert Fitzgibbons Jr., MD:** *Association of Nicotine Cessation Time on the Incidence of Recurrent Incisional Hernia Repair and Postoperative Surgical Site Occurrences*
- **Paul A. Blackburn, DO:** *Synchronized Cardioversion Performed During Cold Water Immersion of a Heatstroke Patient*
- **Jaya M. Raj, MD:** *Optimizing the Internal Medicine Residency Recruitment Process: A National Survey of Program Directors and Next Steps*
- **Dana Chase, MD:** *Dostarlimab for Primary Advanced or Recurrent Endometrial Cancer*
- **Jason Wiseman, MD:** *Is There a Role for Adjuvant Chemotherapy in Pathologic Node-Negative Locally Advanced Rectal Cancer After Neoadjuvant Chemoradiation Therapy*

USING TECHNOLOGY TO ADDRESS RACIAL BIAS IN MATERNAL CARE

A revolutionary project at Creighton University Medical School uses virtual reality (VR) technology to increase racial sensitivity among medical students. Joseph M. Maurice, MD, MS, professor and chair in the department of obstetrics and gynecology, hopes to tackle the pressing issue of health disparities in Black maternal health through innovative training.

Joseph Maurice, MD

Professor and Department Chair OB/GYN

"Ongoing health disparities for Black pregnant and postpartum women are unacceptable," Dr. Maurice says. "Implicit bias and poor cultural competency drive ineffective, inappropriate and racist communication between these women and their providers."

Through this research, Dr. Maurice hopes to provide evidence-based, cost-effective training to address these implicit biases and cultural competencies. Thanks to the VR, the study is very interactive; the student learns how each comment from the physician elicits a response in the patient, with commentary about the underlying misconceptions or microaggressions that lead to communication breakdowns and alienation of the patient.

The project received initial funding in 2022 and has since developed a comprehensive training program that includes a pretest, an immersive VR video viewed through Meta Quest Virtual Reality Headset glasses and a post-test to measure the participants' learning outcomes. The training, which will eventually extend to residents, is meticulously designed to help medical students recognize health inequities experienced by Black, Indigenous, and People of Color (BIPOC) patients, identify and manage their own implicit biases and communicate with BIPOC patients in a respectful and trust-building manner.

ACADEMIC PARTNER

Morehouse School of Medicine

From the genetic epidemiology of cardiovascular disease in ethnic populations to the physiology of sleep disorders, Morehouse School of Medicine leads rigorous basic science, clinical, community health, and policy research to improve the health and well-being of people everywhere. The Morehouse research portfolio in cancer, cardiovascular disease, neuroscience and HIV/AIDS, among other topics impacting underserved communities, is well-established with significant funding from leading research funders such as National Institutes of Health and Centers for Disease Control and Prevention.

Morehouse School of Medicine Research Highlights

- **63 patents established** (between 2009-19)
- **Training and technical assistance** for more than 5,000 primary care providers and rural hospitals in Georgia to adopt and meaningfully use electronic health records.
- **A mobile app health network** and youth coding program empowering young adults to embrace healthy behaviors and reducing the risk of heart disease.
- **Methods for testing** the efficacy and safety of natural herbal extracts that can be used as a treatment for HIV and AIDS to improve patient outcomes around the globe.
- **A student-run clinic** and a self-contained mobile clinical research unit that provides students and investigators unique opportunities to engage more diverse populations in research, particularly in rural communities.

MORE IN COMMON ALLIANCE LEADS HEALTH EQUITY CHANGE

The More in Common Alliance is a 10-year, $100 million dollar partnership between CommonSpirit Health and Morehouse School of Medicine to transform health equity in the U.S. Under the More in Common umbrella, a research workstream led by Dr. Vani Nilakantan, System Vice President Research, CommonSpirit Health, and Dr. Sandra Harris Hooker, Executive Vice Dean Research and Academic Affairs, has been formed and meets monthly to discuss ongoing initiatives.

The overarching goals are to improve diversity, equity and inclusion in research, enhance joint clinical trials, secure national funding and lead innovation together.

In FY24, the group successfully signed a master academic affiliation agreement that will details future collaboration between the entities and establishes framework for ongoing support. In addition, the More in Common Alliance hosts quarterly seminars open to everyone throughout CommonSpirit and Morehouse on topics ranging from research overviews to grant submission.

Looking to the future, the partnership hopes to identify ways to create more research opportunities within CommonSpirit facilities for a diverse population of students, creating a pipeline for improved diversity in all research.

MOREHOUSE SCHOOL OF MEDICINE

ADDRESSING HEALTH INEQUITY THROUGH DIAGNOSTIC INNOVATION

Morehouse School of Medicine researchers currently have two active research projects examining genomic biomarkers to diagnose neurological disease.

The first investigates patterns of RNA expression in patients following an epileptic seizure. “The goal of this study is to identify patterns of RNA expression in blood so we can develop a point of care test to allow an ER physician to determine whether a patient who presents at the ER with a loss of consciousness has had an epileptic seizure, syncope or PNES (psychogenic seizures),” explains Robert Meller, D.Phil. BSc, Professor Neurobiology and Pharmacology. “The accurate diagnosis of such events is critical for timely and cost-effective therapy. Currently there are no tests to accurately retrospectively diagnose a seizure.”

Robert Meller

D.Phil. BSc, Professor Neurobiology and Pharmacology

The study (which has been accepted in Journal of Neurology) shows different types of seizures have different temporal patterns of RNA expression in blood. Using machine learning (ML) algorithms, Dr. Meller and his colleagues hope to use these patterns to accurately predict whether a patient did or did not have an epileptic seizure.

The second study investigates blood RNA expression as a diagnostic biomarker to differentiate hemorrhagic stroke from ischemic stroke and stroke mimic patients. The known effective therapy for stroke is TPA, which dissolves a blood clot (the cause of the stroke in 90% of cases).

“To be given TPA, a hemorrhagic stroke (brain bleed) must be ruled out,” Dr. Meller says. “This is typically done by brain imaging, but imaging delays or living too far from the hospital means that if a patient is not correctly diagnosed and treated with 4.5 hours of the stroke, they cannot be given TPA. We aim to develop a biomarker test with a run time of 30 minutes.”

“Our hope is that the information gained from both studies will enable the development of rapid, cheap genomic biomarker assays that allow us to accurately determine neurological causes of illness (stroke or seizure) in an actionable time frame,” Dr. Meller says. “This is especially useful in locations that suffer from poor health care resources and also typically experience the greatest need.

In the current study, blood is collected at admission from potential stroke patients and analyzed for RNA expression. Using ML approaches, researchers have identified signatures that distinguish ischemic stroke, hemorrhagic stroke and stroke mimics.

OTHER RESEARCH PROGRAMS

Nursing Research

Nurses are uniquely positioned to identify and solve pressing challenges in patient care. Nursing research serves as a pathway to innovative solutions. As evidence is disseminated, evidence-based practice (EBP) is the process of translation and implementation science that enriches clinical practice and policy development.

CommonSpirit Health nurses lead in research as principal investigators, site coordinators, collaborators, and educators of research. All nurses are equipped with the knowledge of EBP to improve practice and patient outcomes.

EVIDENCE-BASED PRACTICE: NURSES MELD RESEARCH WITH CLINICAL EXPERIENCE

For nursing researchers, evidence is being used to guide decision making across CommonSpirit Health and in the clinical space, it begins with a spirit of inquiry. A spirit of inquiry is an ongoing curiosity and questioning of the evidence that guides clinical practice and requires a supportive EBP culture.

CommonSpirit Health has been developing this spirit of inquiry under the direction of Jill Arzouman, DNP, RN, ACNS, BC, CMSRN, NC-BC, System Director Evidence-Based Practice & Implementation Science.

Nurses use evidence-based practice to integrate clinical expertise, patient values and preferences (non-research evidence) with the best available research evidence to inform the decision-making process for patient care.

"Basing practice upon the best available research and non-research evidence improves clinical outcomes, decreases cost and reduces variation," Jill says. "That has the potential to increase patient safety."

Jill Arzouman

DNP, RN, ACNS, BC, CMSRN, NC-BC, System Director Evidence-Based Practice & Implementation Science

Lesly Kelly

PhD, RN, FAAN, Nurse Scientist

Through the EBP process, which includes review, appraisal, and critique of the existing evidence, nurses apply the best available research and non-research evidence to practice to improve outcomes.

When a gap in the evidence is uncovered, nurses conduct research to answer questions and generate new knowledge in areas of health services, patient care, quality of life, and other measurable outcomes. Lesly Kelly, PhD, RN, FAAN, Nurse Scientist, leads federally funded nursing research studies at CommonSpirit and supports research activities across the system.

Examples of nursing research and evidence-based practice are expansive (see Pain Medication Protocol narrative) and address topics ranging from improving communication in patient care rounds, addressing medication safety, decreasing delirium, and removing barriers to patient education.

In addition, integrating evidence helps improve the efficiency of care and reduce expenses for the healthcare organization. Examples include increasing organizational resilience, improving nurse retention, and optimizing workflows and electronic documentation.

NURSING RESEARCH ADDRESSES AN IDENTIFIED GAP IN PAIN MEDICATION ADMINISTRATION

At CHI Health St. Francis in Grand Island, Nebraska, observations made by the nursing team initiated an investigator-derived study led by nurse researchers.

Nurses at CHI Health St. Francis identified an opportunity to impact patient safety in the administration of intravenous push opioid (IVPO) medication and patient monitoring. Using evidence-based practice processes, the team identified a gap in the development and standard use of a protocol for administering IV push opioids.

This observation led to a study led by Brooke Schmitt, MSN, RN, CNML, Director of Patient Care Services, and Jessica Scheideler, BSN, RN, CMSRN, Charge Nurse.

“The goal of the study was to implement an interdisciplinary-created nurse-driven protocol to initiate defined monitoring guidelines based on patient risk factors and the amount of IVPO given to improve patient safety,” explains Jessica.

The implementation of the nurse-driven protocol resulted in increased patient safety through recognizing patient decompensation earlier and decreased naltrexone use.

“Nurses are in the ideal position to recognize opportunities for improving patient care,” Brooke says. “Nurses are driving change through leading research and utilizing evidence-based practice.”

Brooke Schmitt

MSN, RN, CNML,
Director of Patient Care Services,
CHI Health St. Francis

Jessica Scheideler

BSN, RN, CMSRN, Charge Nurse,
CHI Health St. Francis

NURSING RESEARCH AND EVIDENCE-BASED PRACTICE COUNCIL LEADERSHIP

- **La Donna Christy**, PhD, RN, NEA-BC, NPD-BC, CCRN-K, CHSE, System Director, Clinical Education Technology Integration Learning & Organization Development
- **Jodeena Kempnich**, MSN, RN, CNML, Clinical Practice Coordinator
- **Lesly Kelly**, PhD, RN, FAAN, Nurse Scientist
- **Jill Arzouman**, DNP, RN, ACNS, BC, CMSRN, NC-BC, System Director Evidence Based Practice & Implementation Science

Pharmacy Enterprise

The CommonSpirit Pharmacy Enterprise is dedicated to improving medication-related patient outcomes. The Pharmacy Enterprise team engages in research and data development projects in collaboration with our regional, market, and facility pharmacy teams, to align our efforts and to continue to establish our leadership in medication management throughout the continuum of care.

RESEARCH PROJECT TOPICS

- Medication Use
- Care Delivery
- Quality Improvement Initiatives

20+
CommonSpirit Health Sites Participating in Investigational Drug Studies

580+
Investigational Drug Studies (across CommonSpirit)

82
Resident Research Projects Completed by Pharmacy Residency Programs

PHARMACY ENTERPRISE INTEGRAL TO ONE COMMONSPIRIT WORK

The Pharmacy Enterprise team is highly involved in the transition to the One CommonSpirit Epic Gold electronic health record platform.

Our pharmacy teams are involved in aligning how medication records are built, reviewing order sets and medication protocols, developing clinical surveillance and monitoring workflows, and implementing medication inventory and other operational processes.

In addition to Epic Gold, CommonSpirit nursing, SSRM, clinical engineering/capital services, IT and pharmacy are partnering to implement CommonSpirit-wide standard smart infusion pump technology, ensuring all facilities have updated technology for improving medication infusion safety.

PHARMACY DATA WAREHOUSE: USING DATA TO SUPPORT OPERATIONAL AND CLINICAL WORK

One of the priority initiatives of the CommonSpirit Health Pharmacy Enterprise has been to develop a data warehouse to support operational and clinical decision making across the organization. This work is in line with the One CommonSpirit mission, as it strives to align approaches to medication acquisition and reimbursement tracking.

Specific tools which the Pharmacy Enterprise team has developed as part of this initiative include a drug purchasing dashboard, used to determine what medications are being procured across all facilities and clinics, and a non-formulary key performance indicator, which is used to track any medications which have completed clinical review and were determined to be non-formulary. The non-formulary goal for FY24 was 3% or less of drug purchases and the team finished the year at 1.35%.

In addition, the team developed a tool to combine drug billing with patient level claim reimbursement.

Karen McConnell

PharmD, MBA, FCCP, FASHP, BCPS, System Vice President, Pharmacy Enterprise, Chief Pharmacy Officer

"Many medications are provided for treatment or management of disease in an outpatient setting," explains Karen McConnell, PharmD, MBA, FCCP, FASHP, BCPS, System Vice President, Pharmacy Enterprise, Chief Pharmacy Officer.

"These drugs are generally very costly and use is tightly governed by patients' outpatient medical or pharmacy benefits, which are separately reimbursable from any hospital expenses the patient may have had. The separately reimbursable drug dashboard provides insights into what the medications cost the health system, what we get paid by third party payors (Medicare, Medicaid, and Commercial Insurers), and it tracks what the overall margin we receive to ensure we are getting paid for these expensive infusion medications."

The team also created a drug procurement guidance and buying recommendations tool using the data warehouse. This tool helps front line pharmacy workforce identify if there is a lower cost way to procure a particular medication.

A tool to use patient charge data to evaluate medication utilization and using propensity matching is currently in the works. This tool will analyze medication effects in patient outcomes. This quality improvement tool could identify future research opportunities.

OTHER RESEARCH PROGRAMS

Physician Enterprise

The CommonSpirit Health Physician Enterprise represents 6,000 employed and affiliated providers, 1,100 ambulatory care sites, and 24 clinically integrated networks. Physician Enterprise medical groups, physician networks, and population health work are at the core of CommonSpirit's efforts to expand access to primary and preventative care, advocate for those who are poor and vulnerable, and transition to a value-based and coordinated care approach that builds healthier communities and keeps health care affordable.

2023 CommonSpirit Health Physician Enterprise Excellence Awards

"These awards are anchored in our vision statement, 'A healthier future for all — inspired by faith, driven by innovation, and powered by our humanity,'" says Thomas McGinn, MD, Senior EVP and Chief Physician Executive Officer. "They are meant to both honor and recognize the extraordinary work and clinical excellence of colleagues across the Physician Enterprise."

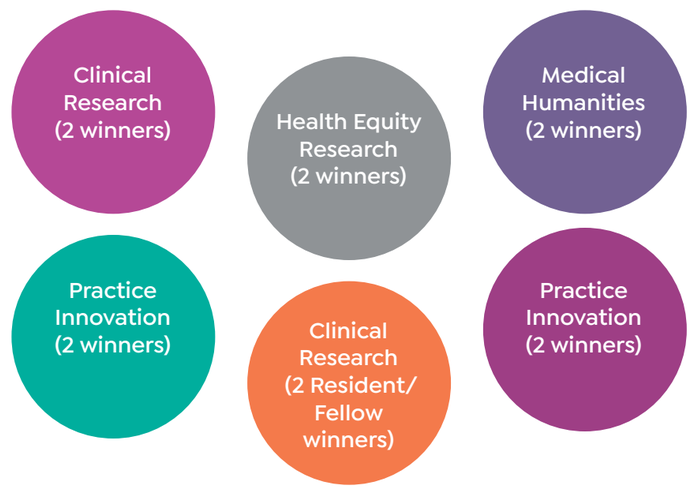
HONORING EXTRAORDINARY WORK: PHYSICIAN ENTERPRISE ACADEMIC EXCELLENCE AWARDS

This year, the Physician Enterprise awarded the 2024 CommonSpirit Health Physician Enterprise Academic Excellence Awards.

The criteria for selection and award were based on articles published in peer-reviewed journals from January to December 2023 and required that the publication had the potential to have a direct, relevant, and high-impact effect on clinical care delivery, with a focus on improving care for our patients and communities.

A new aspect of the program this year included adding three resident/fellow physician trainee awards in the Practice Innovation and Clinical Research categories.

The Academic Excellence Vision Award recognized the following categories:



$500,000 PCORI GRANT SECURED TO SUPPORT EVIDENCE-BASED PRACTICES AND RESEARCH

Late in FY24, CommonSpirit Health was awarded a $500,000 grant by the Patient-Centered Outcomes Research Institute (PCORI) to boost its infrastructure and capacity for implementing evidence-based practices across its vast health care network.

This award, part of PCORI's Health Systems Implementation Initiative (HSII), underscores CommonSpirit's commitment to advancing health care through data-driven and patient-centered approaches. The project, officially titled the HSII Capacity Building Project, aims to address the complex implementation challenges faced by large health systems like CommonSpirit.

Thomas McGinn, MD, Senior EVP and Chief Physician Executive Officer, leads the HSII Capacity Building Project, which will focus on four key areas:

Data Infrastructure
Enhancing data collection, storage, and analysis capabilities to improve reporting and sharing of insights. This will include hiring staff with specialized skills to support these functions.

Analytic Infrastructure
Upgrading software and tools to better analyze data, integrate external data sources, and support rigorous evaluation and publication of results.

Project Management Infrastructure
Strengthening project management processes and resources to streamline the creation, submission, and management of proposals and projects under the HSII framework.

Implementation Readiness
Establishing the Synergistic Implementation Readiness Group (SIRG) to ensure that best practices from PCORI-funded research can be effectively adopted and scaled within CommonSpirit. This group will foster cross-departmental support and enhance the organization's ability to manage large-scale implementation projects.

By enhancing its data and analytic capabilities, project management processes, and readiness for implementation, CommonSpirit aims to drive the adoption of PCORI-funded research and best practices throughout its network.

The project intends to leverage CommonSpirit's existing strengths while addressing critical gaps in its infrastructure. By enhancing its data and analytic capabilities, project management processes, and readiness for implementation, CommonSpirit aims to drive the adoption of PCORI-funded research and best practices throughout its network.

DR. THOMAS MCGINN HONORED FOR RESEARCH AND QUALITY EFFORTS

Thomas McGinn, MD, Senior EVP and Chief Physician Executive Officer was recognized this year by the Agency for Healthcare Research and Quality (AHRQ) for his efforts to improve health care, promote evidence-based medicine, and reduce wasteful spending. Dr. McGinn has a nearly 25-year funding history with the AHRQ, the U.S. federal agency that is charged with addressing the health care quality and safety needs of the nation.

As an internationally distinguished health services researcher with more than 150 scientific publications, Dr. McGinn has focused much of his research and work in clinical prediction models and decision support, reducing unnecessary testing and treatment for the benefit of patient care.

Thomas McGinn, MD,
Senior EVP and Chief Physician Executive Officer

OTHER RESEARCH PROGRAMS

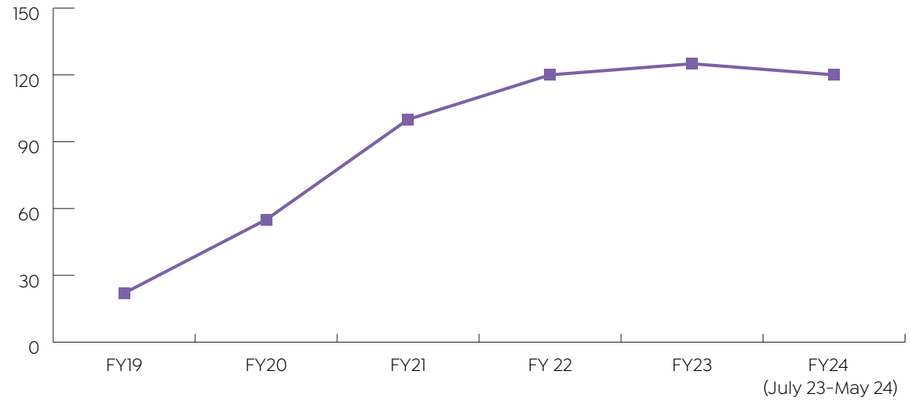
Student and Resident-Based Research

Scholarly research at CommonSpirit Health continues to grow at an impressive rate, with five times more studies underway in FY24 compared to just five years ago. The investigators leading student and resident-based include physicians, medical and pharmacy residents, student learners, service line leaders, and nurse investigators across all regions.

"The future is exciting for trainee and learner research at CommonSpirit Health. Academic and Faculty Affairs, in partnership with the CommonSpirit Health Research Institute, has implemented a collaborative working group focused on aligning and elevating the standards for these research activities across the health system. We look forward to sharing and implementing this work in FY25."

Nana E. Coleman, MD, EdM, System Senior Vice President, Academic and Faculty Affairs, Physician Enterprise

Student and Resident-Based Research Per Fiscal Year



STANDARDIZATION SUPPORTS GROWTH IN STUDENT RESEARCH

Student and resident-based research at CommonSpirit Health has grown significantly, with a notable increase in data-focused studies over recent years.

This surge highlights the organization's commitment to fostering a robust research culture among emerging health care professionals.

"To further enhance this growth, CommonSpirit is working toward implementing a national standardized process for training and evaluating research outcomes," says Lucy Keshishyan, Research Data Specialist. "This initiative aims to ensure consistency, quality, and ethical integrity in all research activities."

By establishing clear guidelines, comprehensive training modules, and continuous support mechanisms, CommonSpirit is dedicated to cultivating a new generation of skilled and impactful health care researchers.

Lucy Keshishyan,
Research Data Specialist

STUDENT RESEARCH SUPPORTS HUMAN TRAFFICKING RESPONSE PROGRAM

CommonSpirit Health's Human Trafficking Response Program equips physicians, advanced practice providers (APPs), and staff to identify and assist patients affected by human trafficking, abuse, neglect, or violence.

These efforts are also evaluated and published on an ongoing basis. For example, in 2018, the Dignity Health Foundation (now known as the CommonSpirit Health Foundation) was awarded a $948,921 federal grant from the Office for Victims of Crime, a part of the U.S. Department of Justice, to expand on and evaluate human trafficking response efforts in Kern County, California.

Arizona State University Collaboration

CommonSpirit partnered with Arizona State University to support several studies examining human trafficking, including:

- Surveying emergency department staff in three hospitals to evaluate the effectiveness of the CommonSpirit PEARR Tool in offering assistance to patients who are identified as victims. In May 2024, these study findings were published in the Frontiers in Medicine.
- Collecting data about patient referrals to a local agency that serves victims of human trafficking and other types of violence. In July 2024, this data was published in a grey literature report available here.
- Interviewing leaders from community-based organizations about the impact of human trafficking response efforts within their communities.In July 2024, this data was published in a grey literature report available here.

The PEARR tool (provide privacy, educate, ask, respect and respond) offers victim assistance to patients in a trauma-informed manner, with the goal of having an informative conversation with patients to promote health, safety, and well-being, and to create a context for affected patients to naturally share their own experiences and possibly accept further services.

Lloyd H. Dean Institute for Humankindness & Health Justice

Over the last year, the Lloyd H. Dean Institute for Humankindness & Health Justice has continued to partner closely with CommonSpirit Health Research Institute in the development and implementation of research efforts that leverage the science of kindness, compassion, empathy and trust to accelerate health justice.

Strategies in Action

The Lloyd H. Dean Institute for Humankindness & Health Justice works with clinicians and partners across CommonSpirit Health to better understand the science of humankindness and its effect on health justice. Current projects include:

Understanding Gaps in Peripheral Arterial Disease (PAD) Screening
Focusing on Equity Gaps (Sacramento, California)
Click here for more information.

Leveraging Digital Patient Navigation
To Address Vaccine Hesitancy in Vulnerable Populations (Central Coast, California, and Little Rock, Arkansas)

Community-led Approach to Increase CKM Awareness (CARES)
Address disparities in cardio-kidney metabolic conditions for African American populations. (Chattanooga, Tennessee, and Omaha, Nebraska)

REFOCUSING TO BE BOLD AND TRANSFORMATIVE

After connecting with many of our clinicians, staff and leaders across the ministry have recognized the importance of supporting the creation of a culture of ***humankindness*** and health justice.

Led by president Alisahah Jackson, MD, the Lloyd H. Dean Institute for Humankindness & Health Justice has undergone a redesign of its strategy and clear call to action to "be bold, establish a transformative and unified health justice framework that acknowledges and removes structural, social and spatial barriers and leverages ***humankindness*** to achieve health and well-being for all."

Through the new strategy, the Institute will support markets and regions throughout the ministry as business partners and foster ***humankindness*** and ensure health justice through education, training, research, and rigorous evaluation. The Institute will accomplish this by empowering our teammates and business partners with knowledge and skills, translating evidence into action, and continually assessing our impact. The Institute is committed to measurably improving health and well-being for all.

Collaborating with Clinicians for Health Justice

It is estimated that Peripheral Artery Disease (PAD) affects between 8.5 and 12 million Americans and its prevalence among adults over 40 years of age is increasing. PAD disproportionately affects Black Americans who, at any age, are twice as likely to experience PAD as their white counterparts but are less likely to be screened and benefit from early diagnosis and treatment.

PAD Provider Survey Results

Primary Care Specialty Most Represented

Respondents Identifying Medical Treatment of Risk Factors as Primary to Treat PAD

Respondents Somewhat or Not Familiar with Racial Disparities in PAD

Respondents Who Rated Their Knowledge of Risk Reduction Therapies as Below Average

IMPROVING HEALTH EQUITY BY IDENTIFYING GAPS IN SCREENING AND TREATMENT FOR PERIPHERAL ARTERY DISEASE

Despite the high prevalence of PAD and the importance of early intervention, screening for PAD remains limited and/or underutilized particularly in primary care settings where most cases of PAD can be identified. This study sought to understand provider knowledge of PAD, associated risk factors, treatment, understanding of disparities in PAD and barriers and facilitators of PAD screening.

It was hypothesized that limited resources, lack of awareness on the part of providers and patients, limitations of training in vascular medicine, and other issues are contributing to PAD morbidity and mortality, particularly among Black and Hispanic populations.

Led by Keith Jones, MD, Dignity Health Medical Foundation (Sacramento, California) vascular surgeon, and Brisa Hernandez, PhD, System Director, Lloyd H. Dean Institute, and a multi-departmental team consisting of Jahmal Miller, CAO, Dignity Health Medical Foundation; Vino Raj, MD, System Director, Research Analytics Center of Excellence; and Akshat Karambe, Senior Analyst, Research Analytics Center of Excellence, the team shared a survey with providers to determine their knowledge, attitude, and beliefs about PAD.

The survey found a lack of knowledge as a key indicator of PAD screening practices, including knowledge on racial disparities in PAD. These identified gaps can inform targeted interventions to improve screening, early detection and treatment of PAD.

Gilead FOCUS: Increasing Access to Vital Screening

Early diagnosis and treatment of Hepatitis C (HCV) and HIV can prevent transmission and health problems that may result from infection. Today, there are highly effective treatment options that can cure more than 90 percent of people with chronic HCV. CommonSpirit Health is committed to pursuing these strategies, particularly in underserved communities where infection rates are high.

FOCUS Program Sites in CommonSpirit Health

CommonSpirit Health currently has California hospital-based sites in Long Beach, Stockton, Kern, Los Angeles and Phoenix (Arizona) participating in FOCUS.

THE FOCUS PROGRAM

- Provides routine screening and testing in emergency departments, primary care, and other settings.
- Normalizes attitudes and de-stigmatize screening and testing, among providers and patients.
- Ensures linkages to community and down-stream resources for access to care and improved health outcomes.

AFFECTING CHANGE IN OUR COMMUNITIES THROUGH GRANT-FUNDED PARTNERSHIPS

CommonSpirit Health's commitment to supporting HIV and hepatitis diagnosis and treatment in vulnerable communities is now brought to life through the Gilead FOCUS (Frontlines of Communities in the U.S.) program.

The grant-funded FOCUS program is a public health initiative that enables partners to develop and share best practices in routine blood-borne virus (HIV, hepatitis C, hepatitis B) screening, diagnosis and linkage to care in accordance with screening guidelines supported by the Centers for Disease Control and Prevention, the U.S. Preventive Services Task Force (USPSTF), and state and local public health departments.

"FOCUS touches on several high priorities for CommonSpirit, including reducing the rates of HIV and hepatitis while also supporting communities experiencing health inequity," explains Tashema Woods-Roberts, Community Educator, Outreach Education. "The FOCUS grant funds help support the cost of personnel, implementation, support services, unreimbursed testing, and much more."

Tashema Woods-Roberts

Community Educator, Outreach Education

In 2023, there were ten CommonSpirit Health sites participating in FOCUS, a large enough sampling that the benefits of centralization became clear.

"In June 2023, we completed a system master agreement with Gilean, centralizing our work with FOCUS and making it easier for our sites to receive internal support," Tashema says. "Both Population Health and the Research Institute provide data support and administrative support, which has been wonderful."

Tashema says clinicians are seeing firsthand the effect of the FOCUS program. "Emergency departments are safety nets for patients who wouldn't normally access health care," she says. "They will come in for emergency care for unrelated reasons, and thanks to the FOCUS program, we can offer screening. We are diagnosing more people and connecting them to the resources and care that they need."

Support for the Future

Research provides opportunity — an opportunity to find a cure, an opportunity to improve quality of life, an opportunity to improve health care for the next generation and an opportunity to provide access to health care for all regardless of race, gender or socio-economic status. Pursuing continued innovation and discovery with the goal of finding new ways to provide effective care for all patients, while ensuring social justice for all is what we do.

HOW YOU CAN HELP: RESEARCH EXCELLENCE EQUITY FUND

The Research Excellence Equity Fund (REEF) supports the intersectionality of research and health equity through multiple mechanisms:

- Clinical Research Innovation Grant Program: A seed grant program as a funding for internal providers and staff to conduct leading edge innovative research that advances care and improves patient lives. Projects must be patient-centered and have a health equity focus/outcome.
- Strategies to enhance diversity in clinical trial and research participation in communities we serve.
- Diversity in research workforce development: Initiatives to increase diversity in the research workforce pipeline through medical student, resident and fellowship research programs for diverse students.
- Start-up funds for research in physician recruitment: Increase physician recruitment capacity for physicians of color by providing funds as start-up for their research projects.

Support to the REEF fund will make a difference today and for generations to come. To give today, visit the REEF website here.

EMPLOYEE GIVING BRINGS ADVANCED EQUIPMENT TO CALIFORNIAN RESEARCHERS

At St. Joseph's Medical Center (Stockton, California), the support of employees is making a tangible difference to researchers.

By donating PTO hours to Mercy Foundation Sacramento, employees were able to raise the funds necessary to purchase a new, refrigerated centrifuge for the St. Joseph's Research Center.

"The purchase will allow the research team to rely less on hospital lab staff, lab equipment and resources," explains Research Manager Lucas Anderson. "The centrifuge will also provide additional capacity to support our growing clinical trial portfolio."

Employees interested in supporting research efforts, either through payroll deduction, PTO donation or single online donation, can visit the REEF website here.

Lucas Anderson,
Research Manager

Members of the California research team gather to celebrate the purchase of a new, refrigerated centrifuge, made possible by employee donations.

Looking to the Future

As with the rest of the CommonSpirit Health ministry, FY24 for the CommonSpirit Health Research Institute was focused on alignment and integration – putting the processes and procedures in place to unify our work and our team members as take the necessary steps toward achieving One CommonSpirit.

Looking to the future, we know that while there is continued work to be done in the alignment process, there are also benefits to be reaped from the work already put in. Increased opportunities for collaboration, improvement to shared tools and resources (including through the rollout of Epic Gold), and enhancements to communication and sharing – these are just a few of the benefits we will continue to build upon as we leverage the breadth and scope of research efforts throughout our organization.

We look forward to sharing successes and discussing opportunities in early 2025, when research and leadership teams from throughout CommonSpirit Health will gather for our next Research Summit at Creighton University (Phoenix, Arizona), Feb. 25-27. This exciting event always inspires and we look forward to experiencing it with you.

LEARN MORE: VISIT OUR WEBSITE

We are proud to share our newly redesigned websites and look forward to continuing to grow this resource in the near future.

Internal Audience
sites.google.com/commonspirit.org/clinicalinstitutes/clinical-institutes-home/research

External Audience
commonspirit.org/research-institute

Board of Directors

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MBA, MHA, FACHE
President, CommonSpirit Health Research Institute

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System EVP, Professor of Medicine, Baylor College of Medicine

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Vani Nilakantan
PhD, System Vice President, Research

Melissa Aigner
BA, System Director, Research Finance

Julie Link
MSW, LCSW, System Director, Sponsored Research Programs

Mary Rydman
MPA, System Director, Research Operations

Jared Rowe
PharmD, System Director Research Operations

Lauren Bacon
BA, Systems Manager Research Integrity, Quality Assurance

Terah Hardcastle
BS, System Manager, Research Program

Vino Raj
MD, MBA, System Director, Research Analytics

Gwen Sapper
MSM, System Manager, Research Finance

Russell Stolp
CIP, CCRP
System Manager, Research Integrity IRB

***Pictured (front row)**: Danielle Hornbuckle, Gwen Sapper, Julie Link, Terah Hardcastle, Vani Nilakantan, Teri Thompson-Seim, Adriane Rubit*
***(middle row)**: Huma Javaid, Jennifer Kohlman, Melissa Aigner, Molly Davis, Dalia Sherif, Lucas Anderson*
***(back row)**: Mary Rydman, Russell Stolp, Jared Rowe, Vino Raj, Randy Holcomb, Sheryl Giambartolomei, Bradford Williams*

Meet Our Team

Office of Research Operations

Bradford Williams
BS, Program Coordinator

Research Analytics Center of Excellence (RACE)

Akshat Karambe
MS, Senior Data Analyst

Brittany Blizzard
Research Grants Program Manager

Lusine Keshishyan
Data Research Specialist

Market Research Managers

Lucas Anderson
Clinical Research Operations

Molly Davis
CHI Health Omaha Research Manager

Joan Galbraith
Market Research Manager

Sheryl Giambartolomei
Market Research Manager

Randy Holcomb
MSE, CCRC
Nebraska Heart Institute Research Manager

Huma Javaid
MS, CCRP

Vikki Jenkins
MHSA, MA, CHRC, CRCP

Adriane Rubit
MBA, CCRP, CHSM, PMP

Dalia Sherif
MBBCh, MS, ACRP-CP

Ginger Whisman
BS, CCRC

CommonSpirit Health Research Institute

Office of Research Integrity and Quality

Preeyam Bisht
MS, Program Specialist IRB

Naomi Gould
BS, Senior Trainer and Educator

Allison Griffin
MS, CIP, Program Specialist IRB

Tara Fisher
Research Training and Education Coordinator

Lusine Keshishyan
IRB Analyst

Jessica Salamacha
BS, CCRC, NRCMA, Senior Analyst Quality Assurance

Office of Research Finance and Accounting

Kathy Brown
Senior Revenue Cycle Analyst

Jessica Pennington
Senior Revenue Cycle Analyst

Viki Ram
MBA, BSBA, Senior Revenue Cycle Analyst

Rebecca Richards
Revenue Cycle Analyst

Office of Research Sponsored Programs, Grants and Contracts

Erin Christian
CRA, CPRA, Pre-Award Specialist Grants

Mary Gulzow
CCRP, Program Specialist

Rita Lerner
BS, CCRP, Contract Specialist

Jennifer McKinley
BS, Grants Business Specialist Post Award

Amber Warrick
BS, Senior Program Analyst

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