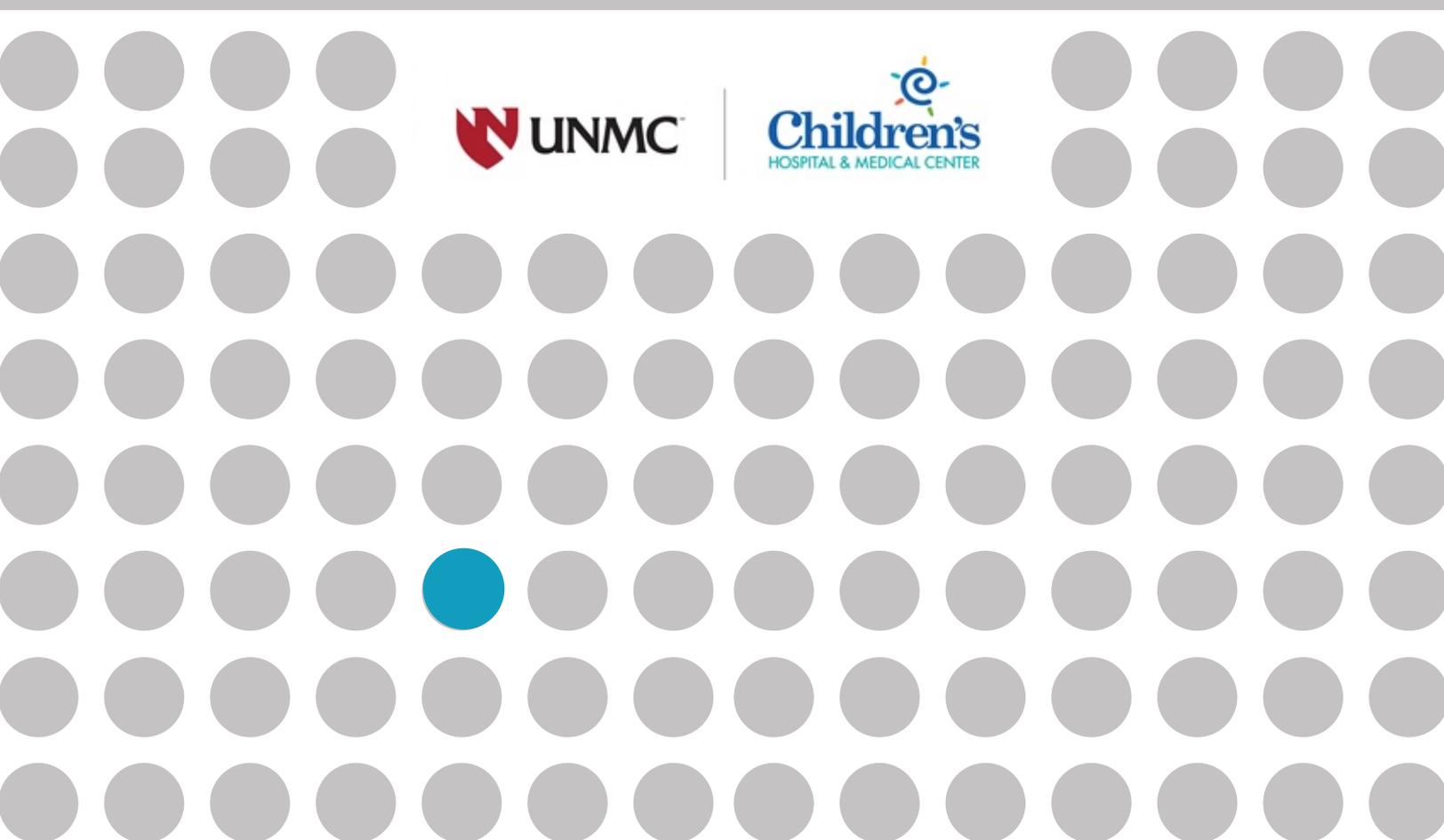


ANNUAL REPORT

2017-2018

NEBRASKA PEDIATRIC CLINICAL TRIALS UNIT

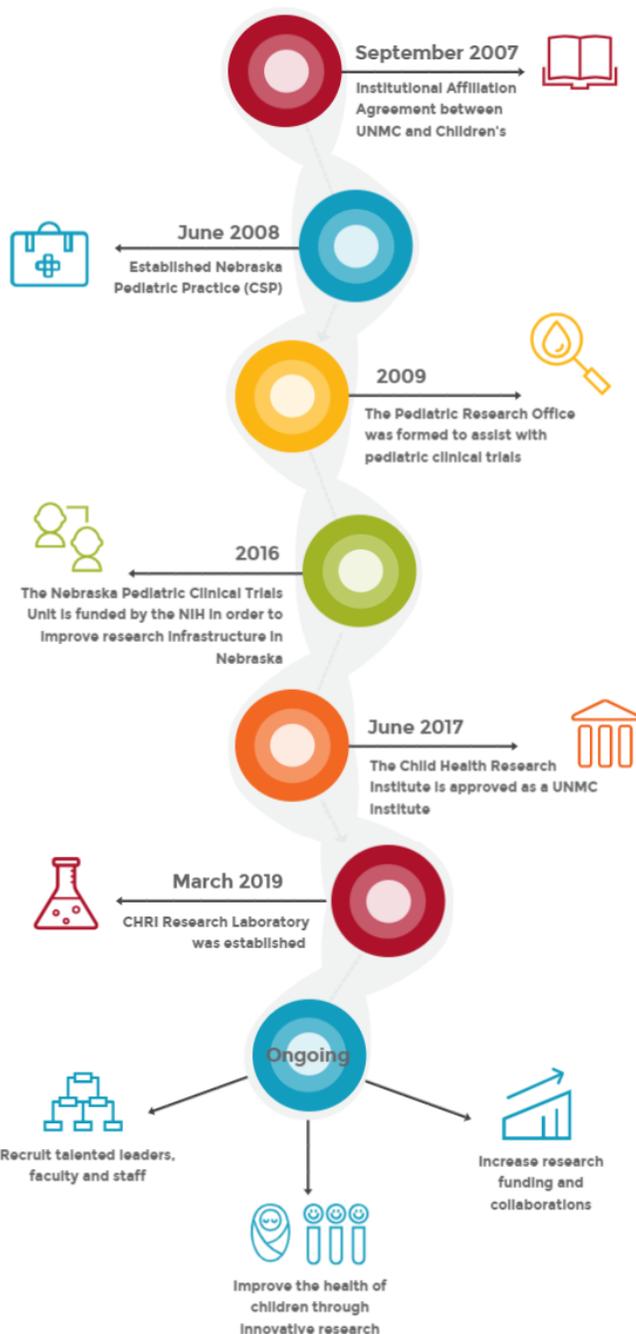
Part of the UNMC Child Health Research Institute



OVERVIEW

- A Brief History
- Current Trends
- Reaching the Children of Nebraska and Beyond
- Technology and Outreach
- Promoting Professional Development
- Building Infrastructure
- Building a Network of Collaborators
- Looking to the Future

A Brief History



In 2007, an affiliation was established between the University of Nebraska Medical Center (UNMC) and Children's Hospital & Medical Center, allowing pediatricians of all specialties to engage in research across both sites. With this increased interest in research came a new need for study support. In 2009, the UNMC Pediatric Research Office (PRO) was established to assist investigators with all aspects of pediatric clinical research. Initially consisting of an administrator and a few study coordinators, the PRO has continued to grow throughout the years and now encompasses a staff of over 20.

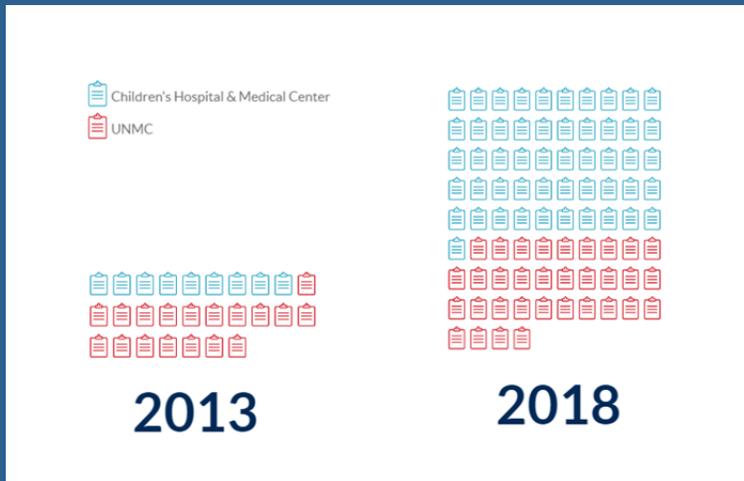
In 2016, UNMC received a grant from the National Institutes of Health to fund the Nebraska Pediatric Clinical Trials Unit (NPCTU). As part of the 17-state IDeA States Pediatric Clinical Trials Network, the NPCTU's mission is to improve research infrastructure throughout Nebraska and to engage rural and underserved populations within the region. Working in close collaboration with the PRO, the NPCTU has placed further emphasis on building institutional infrastructure including faculty development, workflow efficiency, informatics support, networking and outreach.

In parallel, administrators within UNMC and Children's had been working to establish a home for all pediatric research, including basic science, translational research, clinical trials, and more. In June 2017, the Child Health Research Institute (CHRI) was officially approved as a UNMC institute, adding more significant depth and stability to the efforts started 10 years prior. Unifying the PRO and NPCTU under the CHRI umbrella has been a fruitful endeavor. An example of an early achievement is the establishment of the CHRI Research Specimen Laboratory in March 2019. Our team is excited to continue this partnership to establish UNMC and Children's as leaders in pediatric clinical research in the Great Plains region and beyond.

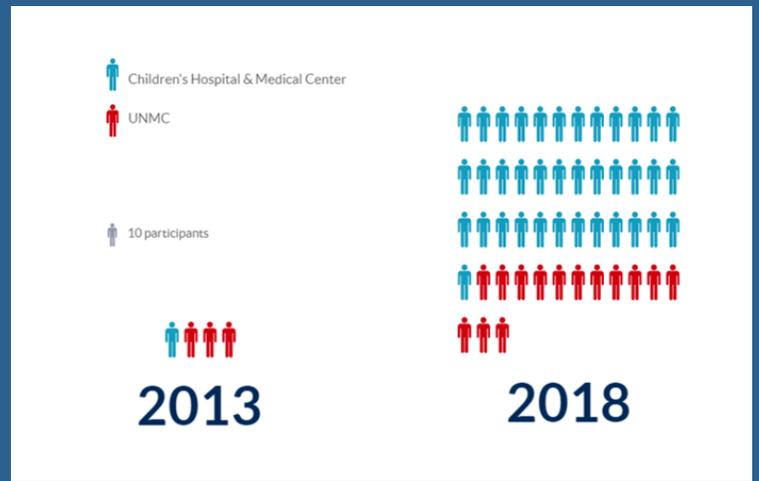
Current Trends

in Pediatric Clinical Research

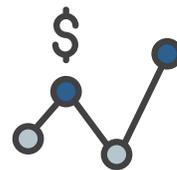
Number of Research Studies



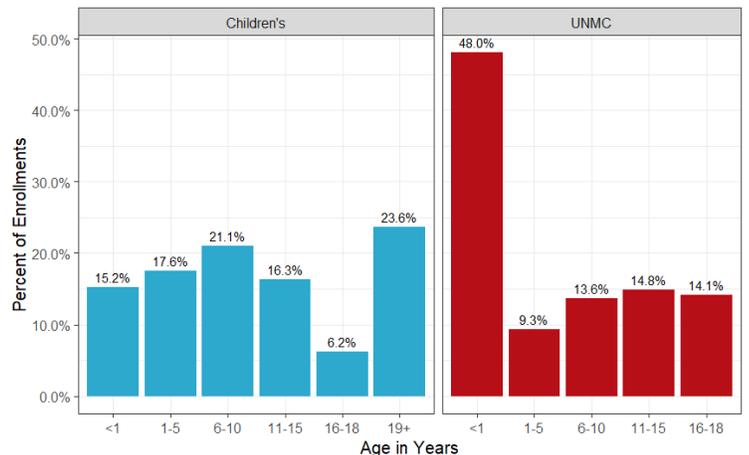
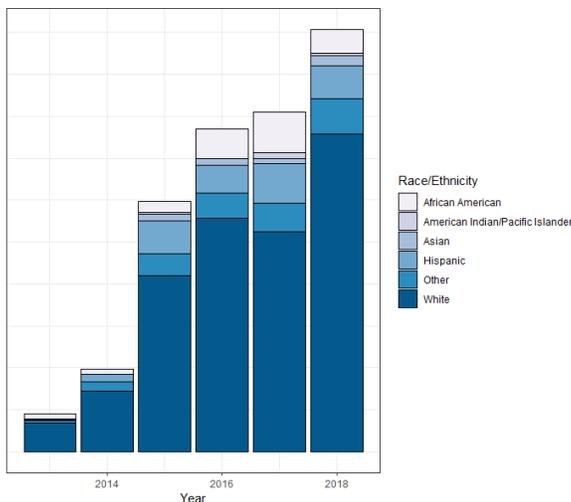
Number of New Participants



Since 2013, there has been a dramatic shift in the research being conducted at UNMC and Children's. In addition to a marked increase in the total number of research studies and total number of new participant enrollments each year, there has been a steady increase in the diversity of participants across all ages, races, and ethnicities.



RESEARCH SPENDING
\$11 Million
in research expenditures in 2018



Research Participants by Race/Ethnicity

Research Participants by Age

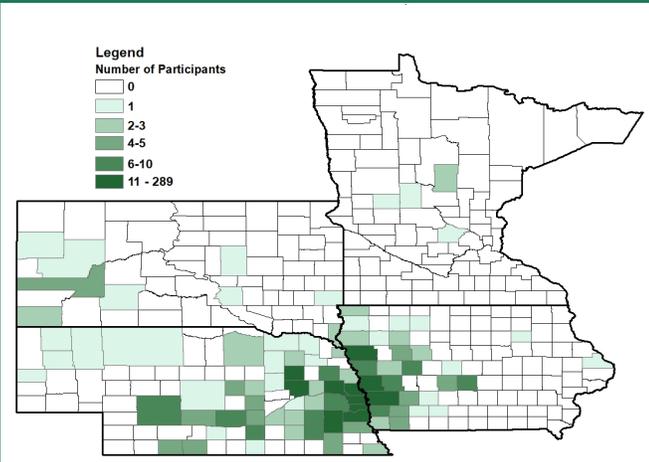


ENGAGEMENT:

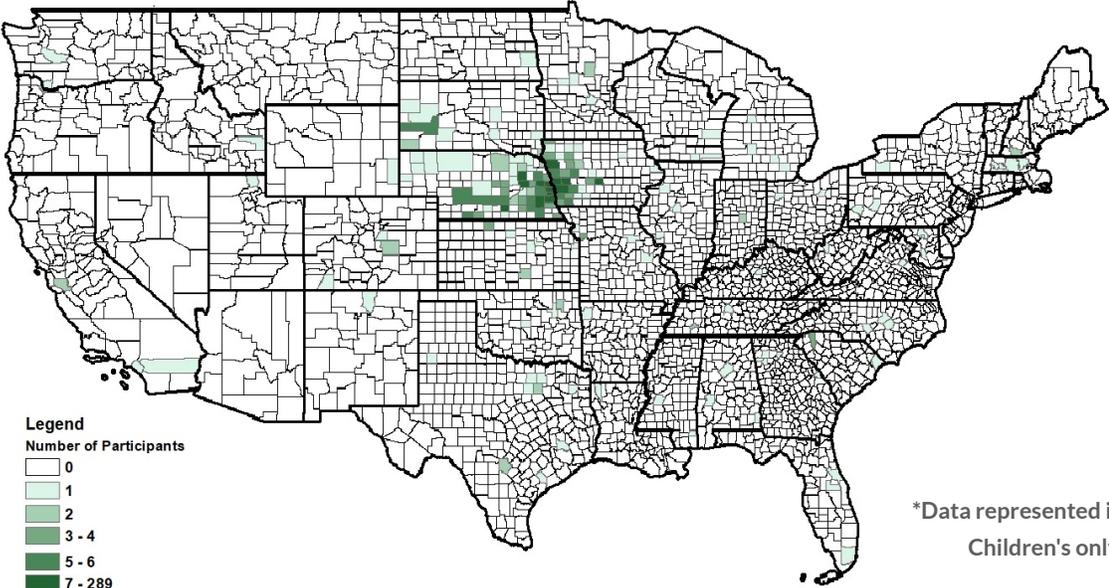
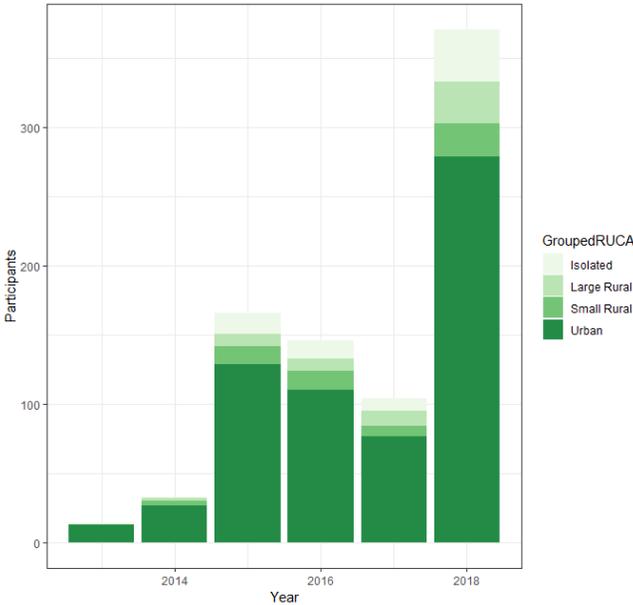
Reaching the Children of Nebraska and Beyond

Research being conducted at UNMC and Children's has positively impacted many communities across our state. Our reach has expanded to our neighbors in the Great Plains region, throughout the United States, and across the globe.

One of the primary objectives of the Nebraska Pediatric Clinical Trials Unit is to improve access of rural and underserved populations to clinical trials, so we anticipate that the number of rural participants will continue to grow alongside CHRI.



Location of Study Participants: Rural vs. Urban



*Data represented is from Children's only

Technology and Outreach

The Nebraska Pediatric Research Registry (NPRR) was created by the NPCTU in order to collect and maintain information from Nebraska families who may want to participate in research in the future. Parents who are interested may register their child(ren) by completing a brief web-based survey designed to collect information regarding their demographics, health interests, and location.

As relevant clinical trials begin enrolling, a member of the NPCTU team provides parents and families with a brief summary of the study, as well as contact information for the investigator and study team. If the study is of interest to them, they may reach out to the study team directly to learn more about the specific screening and consent procedures required to participate, as well as more details about the benefits and risks associated with the study.

A link to the NPRR is found on the CHRI website, and our team has been actively promoting it within the institution, at family practice and pediatric clinics, and at community outreach events. Our hope is that an increased awareness of research, combined with targeted and personalized outreach, will lead to enhanced recruitment and retention for pediatric clinical studies.



SOCIAL MEDIA PRESENCE



The NPCTU established a social media presence in 2016 in order to promote professional development activities, celebrate research achievements, recruit participants for studies, and promote outreach within a variety of Nebraska communities. Early results indicate that studies promoted via Facebook had a dramatic increase in interest from potential participants, so we plan to prioritize and encourage this method of research recruitment going forward.



Total number of posts: **164**

Total followers: **78**

Total reach: **19,448 people**

Total engagement: **754 likes, shares, or follows**

Promoting Professional Development



With the establishment of the Child Health Research Institute, there has been a greater emphasis on the recruitment of research-driven providers across a variety of specialties, specifically within the four pillars of the institute (Cardiology, Oncology, Infectious Disease, and Rare Diseases). In addition, one of the goals of the Nebraska Pediatric Clinical Trials Unit is to 'support the professional development of the associated faculty, residents and personnel conducting clinical research at UNMC and Children's.' The combined efforts of CHRI and the NPCTU have resulted in a total of over 70 active pediatric clinical investigators, the establishment of a research mentorship program, and a new research seminar series designed to highlight and celebrate the work being conducted under our roof.

OVER
70
PEDIATRIC
INVESTIGATORS



2018
Pediatric Research
Forum Submissions

120

EXTERNAL FUNDING

One of the major goals of professional development within CHRI is to equip investigators with the tools and training necessary for competitive grant submissions. As part of these efforts, the PRO has been providing substantial study support to unfunded studies that demonstrate a promising future direction. In addition, the NPCTU has provided funding assistance for several new positions, including a bioinformatics expert, an instructional designer, a human factors specialist, and a grant writer. With the growth of the PRO team and the addition of these staff, we hope to continue to increase the total number of grant submissions as well as the number of successful applications going forward.

Since 2002, the Pediatric Research Forum has been held in May of each year at Children's Hospital & Medical Center. All faculty, fellows, researchers, residents, and students are encouraged to participate. Research posters are displayed in the Atrium at Children's, and topics range from basic sciences to translational research and community studies, showcasing our commitment to help all children live healthy lives. In 2018, there were a record number of abstract submissions, and we anticipate this number to continue to grow as CHRI's emphasis on research continues.



CURRENT STAFF

Pediatric Research Office

To accommodate the increased number of investigators, the PRO has grown significantly since it began in 2009. Current staff includes:

- 16 research coordinators (8 nurse coordinators)
- 2 research assistants
- 1 office assistant
- 1 research lab tech
- 2 research sonographers
- 1 finance specialist
- 1 administrator

2018
FUNDING
\$6 MILLION

Building INFRASTRUCTURE

Previously, samples collected for clinical research at Children's Hospital and Medical Center were processed in the clinical laboratory with their equipment and staff. With the involvement of the NPCTU and Child Health Research Institute, an agreement was reached to acquire space dedicated to pediatric clinical research.

The CHRI Research Specimen Laboratory (RSL) was officially opened in March 2019, and provides investigators access to biospecimen processing and short-term storage resources. In particular, the RSL is designed to allow researchers to conduct FDA-level clinical trials research where obtainment and analysis of blood and other fluid samples are necessary for pharmacokinetic/pharmacodynamic analysis. While not part of the Nebraska Biobank, the RSL can also provide researchers temporary storage of biospecimens prior to shipment to the Nebraska BioBank.

1 Physical Space

The new lab is a secure 300-square-foot space located near the clinical laboratory on the 5th floor of Children's Speciality Pediatric Center.

2 Personnel

A full-time clinical laboratory technician was hired to assist with sample processing and perform other research activities as needed.

3 Equipment

Supported by funding from the National Institutes of Health, the following equipment was purchased for the CHRI Research Specimen Laboratory:

- Deep freezer (-80 degrees)
- Freezer (-20 degrees)
- Under-cabinet refrigerator
- Refrigerated centrifuge
- Microcentrifuge
- Real-time PCR instrument
- Dry ice storage
- Micropipettors
- Other basic lab supplies



NEXT STEPS:

Building a Network of Collaborators



GREAT PLAINS
IDeA | Clinical and
Translational Research

The vision of the Great Plains IDeA Clinical and Translational Research (CTR) program encompasses 'building an effective system and infrastructure to transform and advance clinical and translational research across Nebraska, Kansas, North Dakota, and South Dakota.'

This goal runs parallel to many of CHRI's priorities, which makes this a natural fit for collaborative efforts. The CTR program also shares the Institutional Development Award (IDeA) background of the NPCTU, being funded by the National Institutes of Health to support faculty development and infrastructure in states that are not historically well-funded in research. Our team is excited to work with our colleagues in the Great Plains IDeA-CTR to leverage existing partnerships and identify points for targeted efforts as we aim to improve our reach.

Areas for potential future collaboration include: piggybacking on the CTR's existing practice-based network connections to promote our web-based subject registry; establishing contacts with other institutions in IDeA states in order to coordinate resources and fill gaps in pediatric research; and utilizing an established community advisory board to review proposed studies and provide a voice to advocate for pediatric populations across the region.

NEBRASKA HEALTHY KIDS SUMMIT

PROMOTING HEALTHY EATING AND ACTIVE LIVING IN NEBRASKA COMMUNITIES

Several members of the CHRI and NPCTU teams are involved in planning the first Nebraska Healthy Kids Summit, aimed at engaging community stakeholders across Nebraska in a call to action to address childhood obesity. Our group was tasked with implementing the research fair portion of the event, which will feature poster presentations from researchers across the spectrum of child health and include exhibit tables from organizations that have resources to offer investigators.

We will also lead a skill-building session titled 'Research in Your Community' to assist groups with developing pertinent research questions and identifying potential barriers and resources to assist with their projects. We are anticipating a great turnout and are excited to be a part of this inaugural event!



In order to establish itself as a leader in child health, Children's Hospital & Medical Center created the Children's Health Network (CHN) in 1994. Originally intended as a mechanism for clinical integration and data sharing, it now encompasses over 300 providers in practices across the region.

The Child Health Research Institute has come to the table with leaders of the CHN in order to determine what benefits and services CHRI can offer to network providers. Now in the strategic planning stage, the CHRI team intends to visit 3-4 motivated and high-performing clinical sites to begin building relationships, assessing research interests and identifying infrastructure needs. Our team will use this information to develop relevant professional development tools and assist clinicians by connecting them to projects that align with the needs of their practice and community.



IDeA State Partnerships

Harvey, North Dakota

St. Aloisius Medical Center is a critical access hospital located in Harvey, North Dakota (ND). While ND is an IDeA state, they are not a member of the IDeA States Pediatric Clinical Trials Network and lack access to the resources the network provides. St. Aloisius leadership has expressed interest in collaborating with the Child Health Research Institute to bring pediatric clinical trials to Harvey and the surrounding areas, and there are plans underway to conduct the first in-person site visit this spring.

Looking to the Future



We are committed to our mission to establish Nebraska as a center for cutting-edge pediatric research. As we continue to invest in the future of the Child Health Research Institute, we welcome opportunities for growth, collaboration, and innovation. Please reach out to our team if you have any questions or would like to be a part of our growing team or network of collaborators.

CHILD HEALTH RESEARCH INSTITUTE

Anna Spagnoli, MD, *Executive Director*

William Rizzo, MD, *Scientific Director*

Lisa Runco, MPA, *Administrative Director*

www.unmc.edu/chri

NEBRASKA PEDIATRIC CLINICAL TRIALS UNIT

Russell McCulloh, MD, *Director*

www.unmc.edu/chri/nebraskapedsctu

PEDIATRIC RESEARCH OFFICE

Ashley Servais, MPH, *Manager, Clinical Trials*

NPCTU Grant Administrator

www.unmc.edu/chri/pro

