

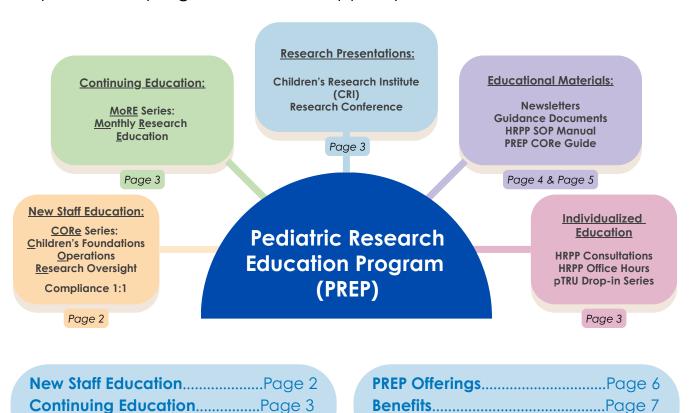
Children's Wisconsin Pediatric Research Education Program

Welcome to the Children's Wisconsin Pediatric Research Education Program (PREP), a multipronged initiative designed to **support** and **empower** clinical research staff through **comprehensive training** and **professional development**.

This program offers a robust variety of new staff education, continuous learning opportunities, novel research presentations, helpful reference materials, and individualized education upon request.

The goal of PREP is to foster a collaborative environment where clinical research staff can **expand their knowledge**, **build connections**, and **stay in the forefront of pediatric research**.

Whether you are just beginning your journey or looking to deepen your expertise, this program is here to support you!



PREP Contacts.....Page 8

Educational Materials.....Page 4 & 5

New Staff Education

PREP <u>CORe</u> Series: <u>Children's Foundations,</u> <u>Operations & <u>Re</u>search Oversight</u>

Children's Foundations

PREP: Children's Foundations is a **full-day**, **in-person** session that covers essential organization-specific content necessary for working in Children's Wisconsin (CW) spaces and engaging with CW patients.

This session features lecture style content, short videos, case studies, article review, group discussion, and live demonstrations to accommodate different learning styles.

Explore topics such as:

- > CW Patient Experience
- > CW Public Safety
- > CW Systems, Resources, & Policies
- > Pediatric Healthcare
- > Applying CW Culture Concepts
- > Professionalism in Research
- > Basic Epic Navigation

Target Audience: All clinical research staff engaging in research at Children's Wisconsin.

Operations

PREP: Operations is a **full-day**, **in-person** session that covers technical content necessary for coordinating research activities, accessing medical records, and collaborating with departments at CW.

This session features lecture style content, lab tours, case studies, group discussion, and live demonstrations to accommodate different learning styles.

Explore topics such as:

- > Research Samples
- Lab and Test Systems
- > Research Order Coordination
- > Children's Lab Services
- > Preparing for Subject Visits
- Informed Consent Processing
- > Epic Research Study Builds

Target Audience: Clinical research staff with patient coordination responsibilities at Children's Wisconsin.

Research Oversight

PREP: Research Oversight is a half-day, virtual session that covers higher-level content relating to organizational regulations, study logistics, feasibility, and claims management.

This session features lecture style content with live polling questions. Learners can join this session virtually from home or their office on campus.

Explore topics such as:

- > Role of the HRPP vs IRB
- > Review Pathways
- > Post Approval Monitoring
- > Protocol Assessment and
- > Operational Feasibility
- > Research Billing Plans
- > Advanced Research Epic

Target Audience: Clinical research staff engaging in research at Children's Wisconsin.

Compliance 1:1

At time of initial Epic access request, new hires meet with Maria Vallejo, Research Compliance Program Manager, to introduce the **role of compliance** in research and share relevant CW policies.

PREP CORe Guide

All staff who attend a CORe session will receive a complimentary PREP Resource Guide to use during sessions and **beyond!**

Find resources such as:

- > CW Policies & Procedures
- > Child Life Resources
- Essential Contacts List
- > CW Language Services
- > CW Acronyms and Lingo
- Campus Maps and Wayfinding



Continuing Education

MoRE Series

The <u>Monthly Research Education</u> (MoRE) series provides continuing education to research staff via Zoom to address **current trends** in research, **new policies** and updates at Children's, and *more!*

Previous topics include:

- > Epic Efficiencies Review
- Navigating Reportable Events at CW
- > Life of a Research Sample
- > CW Research Compliance
- > Risk Based Quality Monitoring
- > Research Notes in Epic
- > CRC Certification
- > Research Billing & Professional Fees

Drop-in Series

The **in-person** Drop-in Series is offered on a monthly basis and provides teams with opportunities to **network** and ask **operational questions** relating to study visit preparation, order coordination, Epic usage, research billing, and more!

» To join the mailing list for the MoRE and Drop-in series, contact TRU-ROS@childrenswi.org.

CRI Research Conference

The CRI Research Conference presents current research studies and novel findings for specific pediatric diseases, advancing our understanding of Child Health Research. This series is offered virtually via Zoom and in-person in the CW Auditorium. MCW designates this activity for up to 1.00 hour of participation for continuing education for allied health professionals.

Learning Objectives:

- Advance knowledge in important pediatric research areas
- Review current understanding and novel findings for pediatric diseases
- Advance understanding in data presentation and data analysis
- To join the mailing list for the CRI Research Conference, contact Jo Ann Callies (<u>JCallies@childrenswi.org</u>)

HRPP Weekly Office Hours

HRPP Virtual Open Office Hours are offered weekly on a first come, first served basis and are designed for study teams who have **general questions** and seek guidance that can be provided quickly.

Virtual Open Office Hours are held every **Tuesday from 9:30AM-11:30AM** via Zoom.

» To schedule an appointment, contact <u>CWHRPP@childrenswi.org</u>.

HRPP Consultations

HRPP Consultations are available to study teams and researchers who have more **complex questions** or issues that may take significant time (>15 minutes) to resolve.

» To schedule a consultation, please complete the <u>Consultation Request</u> Form.

HRPP Individual Offerings

Individualized training may be initiated based on any of the following, or in other circumstances that may warrant additional education:

- To address issues of non-compliance noted during post approval monitoring and review of reportable events submitted by research teams
- > To address issues/gaps in knowledge noted during local context review by HRPP staff or other interactions with research personnel
- At the request of Principal Investigators or other research staff, department, or administrative staff
- To assist in study/feasibility planning for newer investigators and research staff
- > To assist in orienting and onboarding new research staff
- To inform researchers conducting research at Children's Wisconsin of any CW policy or process changes, regulatory changes, general news or information that may affect research
- » To request education from the HRPP, contact <u>CWHRPP@childrenswi.org</u>.

\rightarrow

Educational Materials

HRPP Newsletter

The HRPP regularly publishes a Human Research Newsletter to provide **updates** and **educational offerings** pertaining to CW compliance, regulatory submissions, quality monitoring, and CW policies.

Previous topics include:

- Educational Opportunities
- Continuous Quality Improvement
- > Submission Assistance
- > SMART IRB Reliance
- > RedCap Database
- Compliance Corner
- > eBridge Updates
- Expanded Access Checklists
- To join the mailing list for the HRPP Newsletter, contact CWHRPP@childrenswi.org.



The <u>HRPP SOP Manual</u> contains all **standard operating procedures** relevant to conducting research in Children's Wisconsin (CW) space, using any CW resources, or patients. CW conducts local context review of research prior to IRB review to ensure adherence to all CW SOPs.

This manual Includes SOPs regarding:

- > Quality Assurance
- > Research Determinations
- > IRB Reliance
- Obtaining Informed Consent
- > Vulnerable Subjects in Research
- > FDA-Regulated Research
- > Noncompliance
- > Reporting to Federal Agencies, Departments, Organizational Officials
- Conflicts of Interest
- Participant Outreach
- > HIPAA

In Development...

In addition to the HRPP Newsletters and HRPP SOP Manual, the HRPP has additional resources currently in development.

Resources currently being developed:

- Investigator Manual
- > Virtual modules for researchers





Other Resources

The HRPP offers a **wide range** of resources and guidelines to support study teams, addressing topics such as:

- Consent at Age of Majority
- Consent of Subjects with Limited English Proficiency
- Exempt Research Review Categories
- Protocol Feasibility Checklist
- Pre-submission Checklist/Guidance

Find these resources and **more** on Children's Connect and Intranet.

Educational Materials



TRU Newsletter

The pTRU publishes a monthly <u>newsletter</u> to provide real-time <u>organizational updates</u> pertaining to research, highlight new systems/processes, provide ongoing education, share education and <u>networking opportunities</u>, and spotlight clinical research staff within Children's.

Newsletter Sections include:

- > Friendly Reminders
- > Save the Date Educational Offerings
- > Culture Concepts
- > Trudy Needs Help!
- Did You Know?
- > Cute Moments in the TRU
- Research Partner of the Month
- The Joint Commission (TJC) Updates
- Staff Spotlight



Other Resources

The pTRU has a Florence eBinder located within the MCW Central Resources folder containing pTRU information, guidelines, forms, and general resources for study team reference. These documents can shortcut to individual eBinders as needed and be shared with study sponsors.

References include:

- > TRU Virtual Tour and TRU Map
- > Approved unit SOPs
- TRU Space and Scheduling Guidelines
- Epic Guidance Documents
- > Informed Consent Processing Resources
- > CW New Medical Equipment for Research Form
- Research Order Coordination Guidelines
- > Sample Storage Guidelines
- > pTRU Equipment Records
- > pTRU Newsletters

PREP Offerings

July 2025 - December 2025

July				
М	T	W	TH	F
	1	2	3	4
7	8	9	10	11
14	15	16	17	18
21	22	23	24	25
28	29	30	31	

Augusi					
М	T	W	TH	F	
				1	
4	5	6	7	8	
11	12	13	14	15	
18	19	20	21	22	
25	26	27	28	29	

September					
T	W	TH	F		
2	3	4	5		
9	10	11	12		
16	17	18	19		
23	24	25	26		
30					
	T 2 9 16 23	T W 2 3 9 10 16 17 23 24	T W TH 2 3 4 9 10 11 16 17 18 23 24 25		

October					
М	T	W	TH	F	
		1	2	3	
6	7	8	9	10	
13	14	15	16	17	
20	21	22	23	24	
27	28	29	30	31	

November				
М	T	W	TH	F
3	4	5	6	7
10	11	12	13	14
17	18	19	20	21
24	25	26	27	28

December					
М	T	W	TH	F	
1	2	3	4	15	
8	9	10	11	12	
15	16	17	18	19	
22	23	24	25	26	
29	30	31			

<u>CORe: Children's Foundations</u>

CORe: Operations

CO<u>Re</u>: <u>Re</u>search Oversight

MoRE Series

Drop-ins

HRPP Weekly Office Hours

CRI Research Conference

Note: The schedule above is subject to change. Refer to calendar invites for the most up to date scheduling information.

- For questions regarding CORe Series, MoRE Series, and pTRU Drop-ins, contact <u>TRU-ROS@childrenswi.org</u>.
- For questions regarding HRPP Weekly Office Hours, contact <u>CWHRPP@childrenswi.org</u>.
- For questions regarding CRI Research Conference, contact <u>JCallies@childrenswi.org</u>.

Benefits of Continuing Education

Providing a standardized, organization-specific curriculum is crucial in ensuring study requirements are successfully met, and patient experience and safety are prioritized.

By leveraging continuing education, you can:

Learn new skills

Hone both hard and soft skills. Hard skills pertain Employers that offer continuing education are to job-specific knowledge obtained through formal fraining/education. Soft skills are personal competencies, like effective communication and emotional intelligence. Developing both types of skills is important to reaching both professional and personal goals.

Attract Talent

more likely to attract employees who are interested in striving for excellence. Investing in professional development for employees can grow an existing team's skills and entice new talent to join with the incentive of a clear learning and development plan.

Build Network

Continuing education provides built-in networking opportunities. Workshops, trainings, and webinars are all spaces professionals can meet others within their industry and make new connections. These connections can lead to new opportunities, mentorship, and support which can foster further career development.

Retain Staff

74% of employees say that a lack of development opportunities are preventing them from reaching their full potential, and 94% would stay longer at a company if it invested in staff development. Investing in training programs shows employees that their company is invested in their success.

Boost Confidence

Continuing education can help to bolster employees' confidence in their work. A confident employee is also likely an enthusiastic employee. Confident employees are also more likely to take on challenges. Greater confidence can, in turn, translate into higher overall job satisfaction, performance, and morale.

Develop Leadership

Taking steps to grow and develop skills can encourage employees to pursue leadership opportunities they may not have sought out otherwise. Honing leadership skills empowers employees to lead troubleshooting efforts, propose and implement solutions effectively, and in turn, strengthen their team/program.

Keep Skills Sharp

Industry trends move rapidly, and it's important to keep pace with the times. Ongoing professional development can prevent potential stagnation by maintaining — and improving — skills. **Even the most seasoned staff** require continuing education as systems, policies, and processes evolve over time.

Advance Career

Employees who are invested in professional development display commitment to their work and an interest in continuing to improve. Learning new skills through continuing education reinforces acquired competencies and expands areas of expertise, fostering mental versatility and cross-training.

^{1.} Parsons, Lian. "Why is Professional Development Important?" Professional & Executive Development Harvard Division of Continuing Education, 23 Aug. 2022, https://professional.dce.harvard.edu/blog/why-is-professional-development-important/#What-is-Professional-Development

-> PREP Contacts

Have questions about research education at Children's Wisconsin? Here's who to connect with:



Theresa Kump Director, Clin. Research Operations tkump@childrenswi.org



Lori Roesch Research Integrity Manager Iroesch@childrenswi.org



Tara Murphy Pediatric TRU Manager tmurphy@childrenswi.org



Maria Vallejo Research Compliance Program Manager mvallejo@childrenswi.org



Michelle Martin Quality and Operations Specialist, HRPP mmartin@childrenswi.org



Jeff Crawford Research Operations Specialist, pTRU Research Operations Specialist, pTRU jcrawford@childrenswi.org



Isabella Puls ipuls@childrenswi.org

General questions? Start here:

Human Research Protection Program (HRPP)

cwhrpp@childrenswi.org

Children's Connect: Patient & Community Care > Research > HRPP **Children's Intranet:**

childrenswi.org > Medical professionals > Research > HRPP

CW Corporate Compliance

mvallejo@childrenswi.org

Children's Connect: Patient & Community Care > Research > Compliance

Pediatric Translational Research Unit (pTRU)

TRU-ROS@childrenswi.org

Children's Connect: Patient & Community Care > Research > pTRU Florence:

3.0 MCW Central Res. Binder > 8.0 pTRU