

Department of Pediatrics

Clinical Research Accountability Unit (CRAU)

General Summary

The Department of Pediatrics (DOP) conducts human subjects research through several high-functioning and relatively independent units. The Children’s Research Institute (CRI) within the DOP provides general infrastructure to support human subjects research across the entire Department and promotes alignment and collaboration among each of the units. The Pediatric Clinical Research Unit (Peds CRU) is housed within the CRI and offers full-service study support to any Pediatric investigator, including direct personnel effort.

CRAU Structure

The Pediatrics CRAU will conduct and manage the essential activities outlined below under the direction of the Faculty Director, Administrative Directors, and Program Manager.

CRAU Faculty Director:

- Michelle Hernandez, MD, Faculty Director

CRAU Administrative Directors:

- Suzanne Kennedy, PhD, Administrative Director
- Miriam Davis, RN, BSN, CCRP, Research Program Director

CRAU Program Manager:

- Kate Matthews, Research Program Manager

The Pediatrics CRAU will oversee the Sub-CRAUs listed below. Any research activity that does not fall within a Sub-CRAU designation will be covered by the department-level CRAU.

Sub-CRAU	Faculty & Administrative Leads
Cystic Fibrosis (CF)	Faculty Lead: George Retsch-Bogart, MD
	Administrative Lead: Carol Barlow, RN
Food Allergy Initiative (FAI)	Faculty Lead: Edwin Kim, MD
	Administrative Lead: Lauren Herlihy, RN, MSN, CPNP
Genetics and Metabolism (GM)	Faculty Lead: Joe Muenzer, MD, PhD
	Administrative Lead: Heather Preiss, RN
Neonatology (NICU)	Faculty Lead: Matthew Laughon, MD, MPH
	Administrative Lead: Miriam Davis, RN, BSN, CCRP
Pediatric Hematology/Oncology (HO)	Faculty Lead: Stuart Gold, MD
	Administrative Lead: Juanita Cuffee, MPH
General Pediatric and Adolescent Medicine (GPAM)	Faculty Lead: Kori Flower, MD, MS, MPH

CRAU Essential Activities

The Pediatrics CRAU will maintain accountability for all studies led by Pediatric faculty investigators. Studies conducted within the department that are led by non-Pediatric faculty investigators will be accounted for by the study PI's home department CRAU.

Administration	
Primary point of contact for CRSO and CRAU:	Suzanne Kennedy
Primary point of contact for industry sponsors:	Peds CRU: Miriam Davis CF: Carol Barlow FAI: Lauren Herlihy GM: Heather Preiss NICU: Miriam Davis HO: Juanita Cuffee GPAM: Jennifer Pilotos McBride
Monitor personnel and staffing:	
○ Sub-CRAU level:	Peds CRU: Miriam Davis CF: Carol Barlow FAI: Lauren Herlihy GM: Heather Preiss NICU: Miriam Davis HO: Juanita Cuffee GPAM: Jennifer Pilotos McBride
○ Aggregate CRAU level:	Miriam Davis Michelle Hernandez Suzanne Kennedy
Review study feasibility assessment outcomes:	
○ First-level review:	Peds CRU: Michelle Hernandez CF: George Retsch-Bogart FAI: Edwin Kim GM: Joe Muenzer NICU: Matt Laughon HO: Stuart Gold GPAM: Kori Flower
○ Second-level review:	Michelle Hernandez Stephanie Davis
Review and verify administrative data about the CRAU:	
○ Sub-CRAU level:	Peds CRU: Miriam Davis CF: Carol Barlow FAI: Lauren Herlihy GM: Heather Preiss NICU: Miriam Davis HO: Juanita Cuffee GPAM: Jennifer Pilotos McBride

○ Aggregate CRAU level:	Miriam Davis Suzanne Kennedy
Operations	
Point(s) of contact for OnCore utilization:	Kate Matthews
Pre-review of initial IRB submissions for quality and completeness:	PIs and/or their designees Point of Contact: Kate Matthews
Departmental IRB certification:	Mandy DuPont
Review aggregate audit and monitoring findings:	Miriam Davis Suzanne Kennedy
Financial Management	
Point(s) of contact for financial management best practices:	Peds CRU: Miriam Davis CF: Carol Barlow FAI: Lauren Herlihy GM: Heather Preiss NICU: Miriam Davis HO: Juanita Cuffee GPAM: Jennifer Pilotos McBride

Additional Support Activities Provided by the Pediatrics CRAU

For more information or to request additional support activities, contact Kate Matthews.

Description of Activity	
Coordinator training/mentoring/networking	Miriam Davis Michelle Hernandez
Study start-up, coordination, and management support:	
○ Contract/budget negotiations	
○ Regulatory submissions	
○ Participant recruitment	
○ Study visits	
○ Monitoring visits	Miriam Davis
○ Study close-out	Joe Hatch
○ Sample collection, processing, shipping	Mandy DuPont
○ Program management	
○ Database and form development	
○ Data capture, management, cleaning, analysis	
○ I2b2 queries and CDW data access	
○ Epic chart review	
○ Data use agreements	