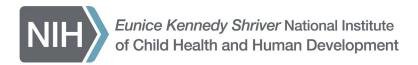
# Leveraging Clinical Trial Networks for advancing therapeutics in pregnancy

Nahida Chakhtoura, MD MsGH Chief, Pregnancy and Perinatology Branch Division of Extramural Research



# Pregnancy and Perinatology Branch Networks



	<u>MFMU</u>	<u>NRN</u>	<u>GN</u>
	Maternal-Fetal Medicine Units Network	Neonatal Research Network	Global Network for Women's and Children's Health Research
		NICHD NEONATAL RESEARCH NETWORK	Global Network for Women's & Children's Health Research
Year Started	1986	1986	2001
Award Length	7 years	7 years	7 years
RFA DCC	RFA-HD-23-017	RFA-HD-23-001	RFA-HD-23-009
RFA Sites	RFA-HD-23-016	RFA-HD-23-002	RFA-HD-23-008

## Department of Health and Human Services

### Part 1. Overview Information

Participating Organization(s)	National Institutes of Health (NIH)	multisite clinical trials		
Components of Participating Organizations	Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)			
	All applications to this funding opportunity announcement should fall within the mission of the Institutes/Centers. The following NIH Offices may co-fund applications assigned to those Institutes/Centers.			
	Office of Research on Women's Health (C	PRWH)		
Funding Opportunity Title	Advance Research for	Multisite Clinical Research: Leveraging Network Infrastructure to Advance Research for Women, Children, Pregnant and Lactating Individuals, and Persons with Disabilities (U01 Clinical Trial Optional)		
tivity Code U01 Research Project Cooperative Agreements		nents		
Announcement Type	New			

• Enhance the rigor and reproducibility of clinical trial protocols

• Promote greater availability of multisite clinical trial infrastructure to support trials from a wider range of

• Facilitate data sharing and access to biospecimens to

· Facilitate greater involvement of diverse populations in

efficiently expand research capacity for all investigators

investigators



# Maternal Fetal Medicine Unit Network

## **Current Sites**





High impact on practice – 25.6% of its papers are cited in medical guidelines





### Tranexamic Acid to Prevent Obstetrical Hemorrhage after Cesarean Delivery

Luis D. Pacheco, M.D., Rebecca G. Clifton, Ph.D., George R. Saade, M.D., Steven J. Weiner, M.S., Samuel Parry, M.D., John M. Thorp, Jr., M.D., Monica Longo, M.D., Ph.D., Ashley Salazar, R.N., M.S.N., W.H.N. P., Wendy Dalton, R.N., Alan T.N. Tita, M.D., Ph.D., Cynthia Gyamfi-Bannerman, M.D., Suneet P. Chauhan, M.D., et al., for the Eunice Kennedy Shriver National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network"

Randomly assigned patients undergoing cesarean delivery at 31 U.S. hospitals to receive either tranexamic acid or placebo after umbilical-cord clamping.

Primary outcome was a composite of maternal death or blood transfusion by hospital discharge or 7 days post partum, whichever came first.

Secondary outcomes were estimated intraoperative blood loss of more than 1 liter (prespecified as a major secondary outcome), interventions for bleeding and related complications, the preoperative-to-postoperative change in the hemoglobin level, and postpartum infectious complications.

CONCLUSIONS Prophylactic use of tranexamic acid during cesarean delivery did not lead to a significantly lower risk of a composite outcome of maternal death or blood transfusion than placebo.

## NuMoM2b Heart Health Study



- NHLBI-funded study established in 2013 to follow participants from original NICHD-funded nuMoM2b study
  - 6000+ participants with diverse backgrounds
- **Key Question**: Do individuals with adverse pregnancy outcomes (APO) have **preexisting** subclinical vascular conditions that are unmasked during pregnancy OR do APOs produce **de novo damage** that predisposes to cardiovascular issues later in life?
- Major findings:
  - Women with APOs at higher risk for hypertension as early as 2-7 years after delivery
  - Significant association of maternal obesity with APOs and cardiovascular health
  - APOs more likely to be a marker of pre-pregnancy CVD risk
- Vital role of pre-pregnancy health for optimal pregnancy and postpartum outcomes





# Global Network

for Women's & Children's Health Research



# **Current Global Network Sites**



# A-PLUS (Azithromycin-Prevention in Labor Use Study) Trial: Reduce Maternal Infection

- Research supported by NICHD's Global Network for Women's and Children's Health Research and Bill and Melinda Gates Foundation
- Tested whether single oral 2-gram dose of the inexpensive antibiotic azithromycin could reduce postpartum sepsis and death
- Enrolled more than 29,000 women in seven lowand middle-income countries
- Study stopped early due to clear maternal benefit
- Results: Single dose azithromycin can reduce by one-third the risk of postpartum sepsis and death
  - Did not reduce the risk of stillbirth, newborn sepsis or newborn death

Tita ATN, Carlo WA, et al. NEJM. (2023)





# Prevention of Iron Deficiency Anemia Post-delivery (PRIORITY Trial)



- Prospective, randomized trial
  - (n = 4800 total)
- Hypothesis: a single infusion of IV iron (maximum of 1g) given in the PP period (6-48 hours after delivery) vs. WHO standard (60 mg of elemental iron taken twice daily x 6 weeks PP) for women with confirmed moderate anemia will reduce anemia at 6 weeks.



# DASH Data and Specimen Hub

- Centralized resource for researchers to share de-identified data from studies funded by NICHD
- Serves as a portal for requesting biospecimens from selected studies in DASH
- Aims to accelerate scientific findings to ultimately improve human health



https://dash.nichd.nih.gov

### **DASH Content**

### **Top Study Topics**

Labor & Delivery Breastfeeding & **Breast Milk\*** Newborn Cerebral Palsy Screening Child Health\* Obesity & Overweight Early Learning Pelvic Floor Early Labor and Birth Disorders Fertility Problems

High-Risk Pregnancy

**HIV/AIDS\*** 

Infant Care &

Health\*

Infant Mortality

Infertility & Fertility

Pharmacology

Pregnancy\*

Preterm Labor

& Birth\* Stillbirth

Women's Health\*

\* biospecimens available

### **Currently Available** Biospecimens

Amniotic fluid Hair

Lymphocytes Blood **Breast Milk** 

**Buffy Coat** Nail

Cord Blood

(Buffy Coat, RBC, Plasma, Serum)

DNA/RN A/Proteins

Environmental Samples

Erythrocytes (RBC)

Meconium

Saliva

Serum/Plasma

Tissue samples

Urine

Vaginal Fluid

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