

# **Maternal, Adolescent, and Pediatric HIV/AIDS Therapeutics Clinical Trials Network:**

## **Pregnant Women in the NIAID HIV/AIDS Clinical Trials Network Recompetition**

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# Setting the 2027 Research Agenda

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- **Every 7 years, NIH competitively reviews its HIV network funding, addressing significant changes in research priorities that have occurred since the last competition**
- **By establishing a forward-looking agenda now, NIH will determine the focus and structure of its HIV clinical trial networks through 2027**



# **Proposing Four Areas of Research Emphasis**

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- **HIV/AIDS Adult Therapeutics**
- **HIV/AIDS Maternal, Adolescent and Pediatric Health Therapeutics**
- **HIV Prevention**
- **HIV Vaccines**

# **Leadership and Operations Center for Maternal, Adolescent, and Pediatric HIV/AIDS Therapeutics Clinical Trials Network**

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**Objective:** To establish a Leadership and Operations Center to carry out the NIAID maternal, adolescent, and pediatric HIV related agenda domestically and internationally in conjunction with Network Laboratory and Statistical and Data Management Centers

**Mechanism:** UM1 (cooperative agreement)

**New/Continuation/Renewal/Expansion:** Renewal

**Duration of award:** 7 years

**Number of awards:** 1 award

**Participating ICs:** NICHD, NIMH, DMID

# **Major Scientific Foci of the Maternal, Adolescent and Pediatric Therapeutics Network**

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- **Novel and durable interventions for treatment of HIV**
- **ART-free remission**
- **Tuberculosis**
- **Complications and co-infections**

# **Novel and Durable Interventions for Treatment of HIV**

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- **Accelerate evaluation (PK, safety, antiviral efficacy) and licensure of promising antiretroviral drugs:**
  - In pediatric HIV-infected populations from newborns to adolescent/young adults
  - In maternal populations including HIV-infected pregnant postpartum and lactating women for optimization of ART for maternal and newborn health and around the critical period of vertical transmission risk
  - Using innovative approaches for rational selection and prioritization of ARVs towards accelerated path to licensure
- **Advance evaluation of long acting and novel drug delivery strategies with extended dosing intervals for HIV-infected maternal, pediatric and adolescent populations**
- **With partners, demonstrate effectiveness of these approaches as integrated behavioral, biomedical, and structural interventions with an emphasis for adolescent populations**

# Tuberculosis

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- **Evaluate (PK, safety, efficacy) new anti-tuberculous drugs and regimens, for treatment and prevention of drug sensitive and drug resistant TB disease**
  - In pediatric and adolescent populations with and without HIV infection
  - In maternal populations including HIV-infected and uninfected pregnant, postpartum and lactating women
- **Within the context of clinical trials or other appropriate settings, evaluate diagnostic, prognostic or treatment response biomarkers for TB disease with a particular focus on young children, non-sputum samples, and suitability for POC platforms**

# Points of Emphasis for Pregnant Women & Children

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- **Get the best drugs for HIV and TB licensed for use in pregnancy**
  - Also get drugs approved across the lifespan (including children and newborns)
- **PrEP and PEP in pregnancy**
  - PEP should be as readily available in pregnancy as treatment is
- **Role of NICHD in defining drug interactions**
  - Drug safety and pharmacology in pregnancy
- **Women specific drug interactions**
  - How are contraceptive hormones altered by HIV and TB medications. Also, how do medications for depression, anxiety, other psychological agents effect and are effected by ART, TB drugs and contraceptives?
- **Improving therapy uptake and adherence in pregnant and breast feeding women. Health systems strengthening, role of BSSR**
- **Prevention in adolescents**
- **New vaccines for childhood diseases such as flu and RSV – IMPAACT led with partnership with DMID/NIAID and NICHD**
- **HIV vaccines across the lifespan. First stop after adults is adolescents. Care must be taken when moving into younger children.**

# Collaborations and Partnerships

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- **Adult therapeutic network: across treatment, ART-free remission and TB scientific areas**
- **HIV prevention network: prevention in adolescents, pregnant and breastfeeding women, biomedical, adherence and other non biomedical approaches**
- **Vaccine network: safety, immunogenicity, or other studies required for product licensure in adolescents and HIV exposed, breastfeeding infants, correlates of vaccine prevention, TB vaccines**
- **Others: Community, DMID, NIH ICs/OAR, Industry/product developers, implementers, regulators and normative bodies**