



Collaborative Initiative for Paediatric HIV Education and Research (CIPHER)

Paediatric Research Grant Programme

Eligible Research Priorities



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CIPHER Grant Programme: Eligible Research Priorities

The Collaborative Initiative for Paediatric HIV Education and Research ([CIPHER](#)) is a two-year International AIDS Society (IAS) initiative to invest in, promote and strengthen paediatric HIV research. One of the two goals of CIPHER is to fund innovative clinical research and operational and implementation science projects focusing on addressing outstanding questions and knowledge gaps regarding how to optimize clinical management of infants, children and adolescents affected by HIV. It also focuses on how existing service delivery approaches and interventions can be enhanced or adapted or new ones developed to improve early uptake in care and retention from infancy to adulthood.

The research focus areas outlined in this document are based on an initial phase of work done by the IAS-Industry Liaison Forum from 2008 to 2010 to identify and define priority HIV research questions for women and children. A detailed environmental scan, [Mapping HIV Research Priorities for Women and Children](#), was published in late 2009. In January 2010, the IAS, in collaboration with a wide range of global partners and stakeholders working in paediatric HIV research, launched a Consensus Statement based on the environmental scan: [Asking the right questions: Advancing an HIV Research Agenda for Women and Children](#).

IAS Research Promotion staff reviewed the analysis and recommendations from the Consensus Statement, conducted a series of interviews with technical expert, studied relevant peer-reviewed articles and conference abstracts (published from January 2010 to July 2012), and consulted with experts from the CIPHER Scientific and Technical Advisory Committee to identify priority clinical and operational research focus areas eligible for funding through CIPHER. Investigators can take a number of different projects, research questions or approaches within any one of these priority focus areas. Eligible focus areas and sample question (intended for illustrative purposes only) are provided below. Projects that do not address clinical or operational research questions within the focus areas outlined will not be eligible for funding.

The CIPHER HIV Paediatric Research Needs Assessment, on which this summary is based, will be published in September 2012; it includes additional information on the studies, expert advice and other inputs that shaped CIPHER and the research focus areas. Other important information about CIPHER, including additional eligibility requirements and deadlines for the CIPHER Grant Programme, is outlined in the [Call for Letters of Intent](#), which is available online at www.ias-cipher.org.



Clinical Research

- Pharmacokinetic (PK) and pharmacodynamic studies of paediatric antiretrovirals and drugs for co-morbid conditions (particularly for TB, malaria, other common childhood illnesses and nutritional interventions for malnutrition).

Sample questions:

- Evaluating Rifampin PK in children on antiretroviral therapy to establish clinical guidance for dosing and formulation
 - Comparing once-daily dosing of ABC and 3TC in infants and children
 - Conducting PK studies of WHO's weight band-based dosing for antiretrovirals
 - Evaluating lead-in NVP dosing in infants – correlating NVP PK, NVP toxicity and virologic control
 - Conducting studies of antiretroviral levels in breast milk of women taking Option B/B+ antiretroviral therapy regimens
- Studies evaluating optimal antiretroviral therapy initiation, long-term management and complications in children (especially those over two years of age) and adolescents.

Sample questions:

- Family-based antiretroviral therapy: operationalizing one pill once daily dosing for all HIV-positive family members - examining uptake and assessing adherence to inform best practice guidance
- Studies evaluating the short-term and long-term impact of *in utero* exposure to maternal antiretroviral therapy and the short-term and long-term impact of paediatric antiretroviral therapy on physical and cognitive development of HIV-infected infants, children and adolescents.

Sample questions:

- Evaluating neonatal outcomes, metabolism, bone mineral density, and other clinically relevant laboratory and biological markers of antiretroviral exposure
 - Evaluating adherence and toxicity outcomes to TDF-based therapy in young children in the context of a national rollout
- Studies evaluating the short-term and long-term impact of *in utero* exposure to maternal antiretroviral therapy on physical and cognitive development of HIV-uninfected children and adolescents.

Sample questions:

- Evaluating bone and renal biochemical profiles among HIV-exposed and uninfected children of mothers on TDF during pregnancy and breastfeeding



- Studies evaluating and/or validating diagnostic assays to assess neurocognitive and physical development among HIV-infected and HIV-exposed uninfected infants and children in resource-limited settings.

Sample question:

- Developing, validating and implementing simple standardized tools/tests for routine cognitive assessment in infants and young children
- Evaluations of the most effective interventions to treat HIV co-infections and co-morbidities among children, including TB, malaria, other common opportunistic infections and malnutrition.

Sample question:

- Defining the essential set of paediatric HIV co-morbidity interventions in the context of Treatment 2.0: how can we best equip primary health care workers to deliver high-quality supportive services in the community for children living with HIV?

Operational Research and Implementation Science

- Evaluations of interventions to improve access to reliable early infant diagnostics, including rapid test protocols.

Sample question:

- Evaluating the feasibility, reliability and sensitivity of a point-of-care early infant diagnosis test performed by different cadres of health care workers in MCH clinics
- Evaluations and/or validation of simplified, standardized diagnostic tools to assess neurocognitive and physical development in HIV-exposed infected or uninfected infants, children and adolescents in resource-limited settings.
- Studies evaluating interventions and optimal models for integrating paediatric HIV services with maternal, newborn and child health and other health services.

Sample question:

- Evaluating the feasibility and impact of providing all routine prenatal maternal and infant PMTCT/FP/MCH services in a single encounter with a health care worker in the health centre on duration of clinic visit and patient satisfaction
- Studies evaluating interventions and optimal models for promoting early post-natal and long-term programme retention and reducing loss to follow up.



- Studies evaluating optimal approaches to supporting childhood and adolescent adherence and transition to adult antiretroviral therapy programmes.

Sample question:

- Studying the effect of different age-appropriate approaches (e.g., cartoon pamphlet) on antiretroviral therapy adherence and on understanding and improving adherence among children aged six to 10 years

- Studies evaluating the most effective interventions to support disclosure, access to psychosocial and sexual and reproductive health services, and delivery of biomedical HIV and STI prevention interventions for adolescents.

Sample question:

- Studying how HIV-positive, sexually active adolescents feel about asking HIV-negative sexual partners to use pre-exposure antiretroviral therapy prophylaxis

