IMPAACT Early Career Investigators
Request for Proposals

Background/Goal: The International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network conducts high quality clinical trials to advance the prevention and treatment of HIV and its complications for infants, children, adolescents, and pregnant/postpartum people globally. This request for proposals is to encourage early career investigators to propose a project that takes advantage of data or samples generated by the IMPAACT Network.

Approved applicants will be expected to present findings at an IMPAACT Annual Meeting and at one or more other scientific meetings. They will also be expected to submit a manuscript to a peer-reviewed journal by the end of the 2-year program period.

Investigators are invited to submit a proposal for funding of work by 3 October 2022.

Eligibility:
Interested applicants must meet the following eligibility criteria:

- Affiliated with the IMPAACT Network
- Holds a current master's degree, doctoral degree, or MD (or local equivalent) and is within 10 years of graduation or fellowship/training.
- Experience either developing or participating in clinical research.
- Support of employer or work institution.
- Proposal uses data or samples from one or more of the studies listed at the end of this solicitation. The protocols may be accessed on the IMPAACT website: https://www.impaactnetwork.org/studies.

Mentors:
Applicants must identify a mentor who has been an investigator on an IMPAACT study and is ideally a current member of an IMPAACT Scientific Committee. Applicants are also encouraged to identify a second mentor from their region and/or institution. If further information is needed or if the applicant has difficulty locating a mentor, the applicant may contact Program Leadership at impaact.earlycareer@fstrf.org.

Parameters:

- This program will only support investigations using existing data and/or stored samples from completed IMPAACT clinical trials (see list at end of this document).
- This program is not intended to (1) develop a new clinical trial, (2) use data and specimens from ongoing studies, or (3) collect prospective data.
- Use of the IMPAACT/ACTG Specimen Repository website for identification of available specimens is encouraged (http://www.specimenrepository.org). If additional assistance is needed beyond the search tools available on the website, the 'contact us' link on the website should be used.
- The proposed work must be completed and submitted for publication within two years. Therefore, location of specimens (if applicable) and required time for obtaining approvals for data use and shipping (e.g., Data Use Agreements, Materials Transfer Agreements), especially internationally, should be considered and will be included in the review process.
- IMPAACT Statistical and Data Management Center statistical support may be requested.
- A brief statement of support from the protocol chair(s) is required. If the proposed analysis has already been completed or is currently underway, the protocol chair will inform the investigator, as that analysis would not be considered eligible for support through this award. For this reason, interested investigators are strongly encouraged to contact the protocol chair before preparing a proposal.
- Funding: A maximum total dollar amount of $100,000 (direct + indirect) is available for each award over a two-year period, which may include level of effort support for the investigator. An additional $25,000 is allowed to support laboratory assays, materials, and shipping of samples to the laboratory of interest, if applicable. Equipment costs cannot be supported.

Inquiries: Inquiries regarding eligibility or other aspects are encouraged prior to submission of applications. Questions may be submitted to impaact.earlycareer@fstrf.org.

Key Dates:

- Proposal Submission Due Date: 3 October 2022
- Anticipated Funding Start Date: 1 December 2022

Submission of Proposals: Proposals must be submitted to impaact.earlycareer@fstrf.org by 5:00 PM ET on the due date. Please use the application template available on https://www.impaactnetwork.org/studies/research-and-study-opportunities.

Applications must include:

- Title of Proposed Investigation (include relevant protocol number in association with the proposal)
- Investigator Information
  - Name and Contact information (include institution, e-mail address)
  - Country of affiliation
  - Self-identified gender and ethnic/racial identification, as comfortable

    - Affiliation with IMPAACT Network or Clinical Research Site
- Research Proposal:
    - Summary of the proposed investigation, including time points for relevant data/specimen, shipment plan for specimens (if any), and associated analysis plans
    - Note if any IRB approvals at their institution are required
    - Note any specific institutions/laboratories that were identified or designated for this work in the approved protocol
    - Note whether the investigators have their own statistician or would like an IMPAACT statistician (either through the Statistical and Data Analysis Center or the Social Behavioral Sciences Core) to work on the project
- Expected deliverables/timeline for completion within the funding period; this should include completion of laboratory assays (if any), data analysis, and manuscript preparation
- Budget and Justification:
    - Provide the budget and justification for the entire funding period, as an Appendix
    - Attendance at the IMPAACT Annual Meeting in Washington, DC is required and must be included in budget. Additional travel and conference registrations should also be included
    - IMPAACT statistician time need not be included in the budget
    - Optional: Note any outside resources available to the investigator that may contribute to the success of the investigation; e.g., institutional support, grant or foundation support
    - Note, funding is a cost-reimbursement sub-agreement.
- Letters of Support to be included:
    - A brief statement of support from the Protocol Chair(s)
    - A brief statement of support from the proposed mentor(s)

Eligible Studies:

As noted above, proposals may be submitted for the studies listed below. If the study of interest is not listed below, please contact impaact.earlycareer@fstrf.org.

- P1070: Dose-Finding and Pharmacogenetic Study of Efavirenz in HIV-Infected and HIV/TB Co-Infected Infants and Children >= 3 Months to <36 Months of Age
- P1078: A Phase IV Randomized Double-Blind Placebo-Controlled Trial To Evaluate the Safety of Immediate (Antepartum-Initiated) Versus Deferred (Post Partum-Initiated) Isoniazid Preventive Therapy Among HIV-Infected Women In High TB Incidence Settings
- 1077BF (PROMISE): Breastfeeding Version of the PROMISE Study
- 1077FF (PROMISE): Formula Feeding Version of the PROMISE Study
- P1090: A Phase I/II, Open-Label Trial to Evaluate the Safety, Tolerability, Pharmacokinetics and Antiviral Activity of Etravirine (ETR) in Antiretroviral (ARV) Treatment-Experienced HIV-1 Infected Infants and Children, Aged >=2 Months to <6 Years
- P1092: Phase IV Evaluation of the Steady State Pharmacokinetics of Zidovudine, Lamivudine, and Lopinavir/Ritonavir in Severely Malnourished HIV-1-Infected Children
- P1097: Raltegravir Pharmacokinetics and Safety in Neonates

- P1101: Phase I/II Dose-Finding, Safety, Tolerance and Pharmacokinetics Study of a Raltegravir-Containing Antiretroviral Therapy (ART) Regimen in HIV-infected and TB Co-infected Infants and Children
- P1104s: Longitudinal Developmental and Neuropsychological Assessments of HIV-Infected Participants of P1060 and HIV-Uninfected Controls
- P1110: A Phase I Trial to Evaluate the Safety and Pharmacokinetics of Raltegravir in HIV-1-Exposed Neonates at Risk of Acquiring HIV-1 Infection
- IMPAACT 2001: A Phase I/II Trial of the Pharmacokinetics, Tolerability, and Safety of Once-Weekly Rifapentine and Isoniazid in HIV-1-infected and HIV-1-uninfected Pregnant and Postpartum Women with Latent Tuberculosis Infection
- IMPAACT 2002: Combined Cognitive Behavioral Therapy and a Medication Management Algorithm for Treatment of Depression among Youth Living with HIV in the Unites States
- IMPAACT 2007: Phase I Safety and Pharmacokinetic Study of Maraviroc in HIV-1-Exposed Infants at Risk of Acquiring HIV-1 Infection
- IMPAACT 2013: Phase I Placebo-Controlled Study of the Infectivity, Safety and Immunogenicity of a Single Dose of a Recombinant Live-Attenuated Respiratory Syncytial Virus Vaccine, D46/NS2/N/deltaM2-2-HindIII, Lot RSV#011B, Delivered as Nose Drops to RSV-Seronegative Infants 6 to 24 Months of Age
- IMPAACT 2010 (VESTED): Phase III Study of the Virologic Efficacy and Safety of Dolutegravir-Containing versus Efavirenz-Containing Antiretroviral Therapy Regimens in HIV-1-Infected Pregnant Women and Their Infants
- IMPAACT 2015: Evaluation of the HIV-1 Reservoir in the Central Nervous System of Perinatally-Infected Youth and Young Adults with Cognitive Impairment
- IMPAACT 2018: Randomized Phase I Study of the Infectivity, Safety, and Immunogenicity of a Single Dose of the Recombinant Live-Attenuated Respiratory Syncytial Virus (RSV) Vaccines RSV deltaNS2/delta1313/I1314L or RSV 276 or Placebo, Delivered as Nose Drops to RSV-Seronegative Infants 6 to 24 Months of Age
- P1066: A Phase I/II, Multicenter, Open-Label, Noncomparative Study of the International Maternal, Pediatric, Adolescent AIDS Clinical Trials (IMPAACT) Group to Evaluate the Safety, Tolerability, Pharmacokinetics, and Antiretroviral Activity of Raltegravir (Isentress(TM), MK-0518) in HIV-1 Infected Children and Adolescents
- P1072: Safety and Immunogenicity of a Live, Attenuated Rotavirus Vaccine (RotaTeq^(TM)) In HIV-1 Infected and Uninfected Children Born To HIV-1 Infected Mothers
- P1074: A Prospective Surveillance Study of Long Term Outcomes in HIV-Infected Infants, Children, and Adolescents
- P1068s: P1060 Substudy Comparing Differences in Malaria Parasitemia by Real Time Quantitative PCR in HIV-Infected Infants and Children on PI-Based HAART Versus NNRTI-Based HAART
- P1076: Impact of Oral Alendronate Therapy on Bone Mineral Density in HIV-Infected Children and Adolescents with Low Bone Mineral Density
- P1079: Pharmacology of Artemisinin-Based Antimalarial Therapy Within the Context of Antiretroviral Therapy

- P1083: A Phase II/III Trial of Lopinavir/Ritonavir Dosed According to the WHO Pediatric Weight Band Dosing Guidelines
- P1058A: Intensive Pharmacokinetic Studies Of New Classes Of Antiretroviral Drug Combinations In Children, Adolescents and Young Adults
- P1085: Duration of Human Papilloma Virus (HPV) Type-Specific Antibody After Administration of Quadrivalent HPV Vaccine to HIV-1 Infected Children Previously Enrolled in P1047
- P1094: Evaluation of 3TC or FTC Monotherapy Compared to Continuing HAART as a Bridging Antiretroviral Strategy in Persistently Non-Adherent Children, Adolescents, and Young Adults Who are Failing HAART and Have the M184V Resistance Mutation
- P1096: 1 Study to Determine the Safety, Infectivity, Immunogenicity and Tolerability of 2 Doses of Live Attenuated Recombinant Cold-passaged (cp) 45 Human Parainfluenza Type 3 Virus Vaccine, rHPIV3cp45, Lot PIV3#102A, Delivered as Nose Drops to HPIV3-Seronegative Infants and Children 6 to 36 Months of Age, at a 6 Month Interval
- P1114: A Phase I Study of the Safety and Immunogenicity of a Single Dose of the Recombinant Live-Attenuated Respiratory Syncytial Virus Vaccine RSV cps2, Lot RSV#005A, Delivered as Nose Drops to RSV-Seronegative Infants and Children 6 to 24 Months of Age
- IMPAACT 2000: A Phase I Study of the Safety and Immunogenicity of Recombinant Live-Attenuated Respiratory Syncytial Virus Vaccine RSV LID deltaM2-2 in RSV-Seronegative Infants and Children
- IMPAACT 2011: Phase I Placebo-Controlled Study of the Infectivity, Safety and Immunogenicity of a Single Dose of a Recombinant Live-Attenuated Respiratory Syncytial Virus Vaccine, LID DeltaM2-2 1030s, Lot RSV#010A, Delivered as Nose Drops to RSV-Seronegative Infants 6 to 24 Months of Age
- IMPAACT 2012: Phase I Placebo-Controlled Study of the Infectivity, Safety and Immunogenicity of a Single Dose of a Recombinant Live-Attenuated Respiratory Syncytial Virus Vaccine, LID cp delta M2-2, Lot RSV#009B, Delivered as Nose Drops to RSV-Seronegative Infants 6 to 24 Months of Age
- P1043: III Randomized Trial of The Safety and Efficacy of Three Neonatal Antiretroviral Regimens for Prevention of Intrapartum HIV-1 Transmission
- P1025: Perinatal Core Protocol
- P1041: A Randomized, Double Blind, Placebo Controlled Trial to Determine the Efficacy of Isoniazid (INH) in Preventing Tuberculosis Disease and Latent Tuberculosis Infection Among Infants with Perinatal Exposure to HIV
- P1020A: Phase I/II, Open-Label, Pharmacokinetic and Safety Study of a Novel Protease Inhibitor (BMS-232632, Atazanavir, ATV, Reyataz TM) in Combination Regimens in Antiretroviral Therapy (ART)-Naïve and Experienced HIV-Infected Infants, Children, and Adolescents
- P1055: Psychiatric Co-morbidity in Perinatally HIV-Infected Children and Adolescents
- P1058: Intensive Pharmacokinetic Studies of Antiretroviral Drug Combinations in Children
- P1045: Prevalence of Morphologic and Metabolic Abnormalities in Vertically HIV-Infected and Uninfected Children and Youth

- P1060: Phase II, Parallel, Randomized, Clinical Trials Comparing the Responses to Initiation of NNRTI-Based Versus PI-Based Antiretroviral Therapy in HIV-Infected Infants Who Have and Have Not Previously Received Single Dose Nevirapine for Prevention of Mother-to-Child HIV Transmission
- P1065: Phase I/II Study of Safety and Immunogenicity of Quadrivalent Meningococcal Conjugate Vaccine in HIV-Infected Children and Youth (Versions 1.0 – 3.0) And Open Label Immunogenicity Study of a Booster Dose of MCV4 in Previously Immunized HIV-Infected Children and Youth