Request for Proposals: Secondary/Exploratory Study Objectives

**Background/Goal:** To encourage and support rapid pursuit of secondary and exploratory study objectives in IMPAACT studies that were closed to follow-up within the last five years and for which the primary analyses have been completed, investigators are invited to submit a brief proposal for funding of work that can be completed by 3 November 2017.

*Note that this is not the only opportunity for study teams to carry out protocol-specified secondary or exploratory objectives: approval from the IMPAACT Management Oversight Group may be sought at any time for associated investigations requiring additional resources.*

**Eligibility:**
- Proposals may be submitted for the following studies: P1020A, P1058A, P1060, P1063, P1065, P1070, P1073, P1074, P1079, P1080, 1077HS, 1077BF/FF, P1084s, P1085, P1094, P1114, and IMPAACT 2000; full titles are provided at the end of this solicitation. The protocols may be accessed on the IMPAACT website: [http://impaactnetwork.org/studies/index.asp](http://impaactnetwork.org/studies/index.asp). MS Word versions may be requested from the IMPAACT Operations Center at IMPAACT.OperationsCenter@fstrf.org.
- Priority will be given to investigators who have served as members of the respective protocol teams.

**Limitations/Parameters:**
- This program will only support investigations specifically identified in a protocol as a secondary or exploratory objective.
- Secondary objectives as stated in protocols and approved by IRBs/ECs cannot be changed; proposed work must be consistent with the relevant protocol document and associated informed consent forms. Depending on the specificity of the language, there may or may not be leeway to use more up-to-date assays/methods than originally planned.
- This program will not support objectives associated with ongoing studies or collection of prospective data.
- The proposed work must be completed by 03 November 2017. Therefore, location of specimens (if applicable) and required time for obtaining approvals for shipping (e.g. 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 analyses associated with an objective in which a potential applicant is interested have already been completed or are currently underway, the protocol chair will inform the investigator, as that objective 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 $150,000 is available for each award. Funding may include LoE support for the investigator, laboratory assays and 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 strongly encouraged prior to submission of applications. Questions may be submitted through the IMPAACT Operations Center at IMPAACT.OperationsCenter@fstrf.org.

Key Dates:
- Proposal Submission Due Date: 6 March 2017
- Anticipated Funding Start Date: 10 April 2017

Submission of Proposals: Proposals must be submitted through the IMPAACT Operations Center at IMPAACT.OperationsCenter@fstrf.org by 5:00 PM ET on the due date.

Application Format/Outline (Maximum 2 pages, exclusive of appendices)

Title of Proposed Investigation (to include relevant protocol number)

Investigator Information
- Name and Contact information (include institution, e-mail address)
- Affiliation with protocol team

Research Proposal
- Relevant secondary/exploratory objective(s) exactly as stated in the approved study protocol
- Rationale for pursuit of this objective: Include both a) the original rationale included in protocol and b) rationale for why the investigation is still considered a priority (noting any more recent references).
- Summary of the proposed investigation, including time points for relevant data/specimen required from the protocol, shipment plan for specimens (if any), and associated analysis plans that were included in the protocol document.
  - 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 to work on the project.
- Expected deliverables/timeline for completion within the funding period. This should, ideally, include completion of laboratory assays (if any), data analysis and manuscript preparation.

Budget and Justification
- For evaluation/illustrative purposes, provide the budget and justification for the entire funding period (total costs of maximum $150,000 - 10 April 2017 through 03 November 2017, as Appendix 1. IMPAACT statistician time need not be included in the budget.
- Optional: Note any outside resources that available to the investigator that may contribute to the success of the investigation; e.g., institutional support, grant or foundation support.

Letter of Support
- A brief statement of support from the Protocol Chair(s) must be included as Appendix 2.
Eligible Studies

As noted above, proposals may be submitted for the studies listed below. The protocols may be accessed on the IMPAACT website: [http://impaactnetwork.org/studies/index.asp](http://impaactnetwork.org/studies/index.asp). MS Word versions may be requested from the IMPAACT Operations Center at [IMPAACT.OperationsCenter@fstrf.org](mailto:IMPAACT.OperationsCenter@fstrf.org).

- P1020A: A Phase I/II, Open-Label, Pharmacokinetic and Safety Study of a Novel Protease Inhibitor (BMS-232632, Atazanavir, ATV, Reyataz) in Combination Regimens in Antiretroviral Therapy (ART)-Naïve and Experienced HIV-infected Infants, Children and Adolescents
- P1058A: Intensive Pharmacokinetic Studies of New Classes of Antiretroviral Drug Combinations in Children, Adolescents, and Young Adults
- 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
- P1063: Phase I/II Safety and Efficacy Investigation of Atorvastatin for Treatment of Increased LDL-Cholesterol in HIV-Infected children, Adolescents, and Young Adults
- P1065: Phase II Study of Safety and Immunogenicity of Quadrivalent Meningococcal Conjugate Vaccine in HIV-Infected 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 (Version 4.0)
- P1070: Dose Finding and Pharmacogenetic Study of EFV in HIV-Infected and HIV/TB Co-infected Infants & Children >=3 months to <36 Months of Age
- P1073: Study of Immune Reconstitution Inflammatory Syndrome (IRIS) for International Sites Initiating Highly Active Antiretroviral Therapy (HAART) in Infants and Children <72 Months of Age
- P1074: A Prospective Surveillance Study of Long Term Outcomes in HIV-infected Infants, Children and Adolescents
- P1079: Pharmacology of Artemisinin-Based Antimalarial Therapy Within the Context of Antiretroviral Therapy
- P1080: A Pilot Study of Psychiatric and Antiretroviral Medication Concentrations in HIV-1 Infected and Uninfected Children and Adolescents
- 1077BF/FF: Breastfeeding/Formula Feeding Versions of the PROMISE Study: Promoting Maternal and Infant Survival Everywhere
- P1085: Duration of Human Papilloma Virus (HPV) Type-Specific Antibody After Administration of Quadrivalent HPV Vaccine to HIV-infected Children
- 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
- 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 delta M2-2 in RSV-Seronegative Infants and Children