From: IMPAACT Operations Center
To: IMPAACT Operations Center
Subject: IMPAACT Network Guidance for Resuming Accrual in Select Studies during the COVID-19 Pandemic
Date: Tuesday, July 21, 2020 9:45:41 AM

Dear IMPAACT Network Colleagues –

The safety and well-being of study participants, clinical research site staff, laboratory staff, and community members remain of paramount importance and the highest priority for the IMPAACT Network. We know that many of you are continuing to face unprecedented challenges associated with the COVID-19 pandemic and that you are working tirelessly to support and safeguard your patients, research participants, site staff, families, and communities.

In consultation with the Division of AIDS and other NIH partners, the IMPAACT Management Oversight Group (MOG) has identified the first set of studies to initiate or resume accrual. Balancing site capacity and potential study benefits and risks, the MOG has agreed that participant accrual into the studies below can be resumed, with key study-specific caveats:

- IMPAACT 2019, *Phase I/II Study of the Pharmacokinetics, Safety, and Tolerability of Abacavir/ Dolutegravir/Lamivudine Dispersible and Immediate Release Tablets in HIV-1-Infected Children Less than 12 Years of Age*
- IMPAACT 2005, *A Phase I/II Open-label, Single-Arm Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of Delamanid in Combination with Optimized Multidrug Background Regimen (OBR) for Multidrug-Resistant Tuberculosis (MDR-TB) in HIV-infected and HIV-uninfected Children with MDR-TB*
- Steps 1 and 2 of IMPAACT P1115, *Very Early Intensive Treatment of HIV-Infected Infants to Achieve HIV Remission: A Phase I/II Proof of Concept Study*
- IMPAACT P1108, *A Phase I/II, Open-Label, Single Arm Study to Evaluate the Pharmacokinetics, Safety and Tolerability of Bedaquiline (BDQ) in Combination with Optimized Individualized Multidrug-Resistant Tuberculosis (MDR-TB) Therapy in HIV-Infected and HIV-Uninfected Infants, Children and Adolescents with MDR-TB Disease*

Prior to resuming accrual, the CRS Leader at each site will be required to complete an attestation for Network review and approval. The Operations Center will soon be reaching out to sites participating in these studies to begin the process. Sites should not feel pressured to resume enrollment in these studies until they are comfortable doing so and confident that this can be done safely for participants, staff, and their communities.

Sites are also encouraged to work with local programs to facilitate access to the best available local standard vaccine series for children on study and newly enrolled.

The MOG is continuing to discuss the timelines for resumption of accrual in other studies and will be in communication with those teams when additional information is available. We will continue to monitor the pandemic closely and will provide updates as needed. Please contact us with any questions and concerns. Very special thanks to all site staff and community partners for your

continuing efforts on behalf of the Network and for keeping the its important research moving forward!

IMPAACT Operations Center