



17 March 2020

Reference: Guidance on Study Activities during Coronavirus/COVID-19 Pandemic

Dear IMPAACT Colleagues –

The safety and well-being of study participants, clinical research site staff, and laboratory staff are of paramount importance and the highest priority for the IMPAACT Network. We know that many of you are facing 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.

The Division of AIDS has issued the attached guidance to its HIV/AIDS research networks. Consistent with this guidance, and in consultation with our NIH partners, the IMPAACT Management Oversight Group (MOG) has made the following decisions regarding the conduct of IMPAACT studies, effective immediately and until further notice:

- No new studies (or new study arms or components) will be opened to accrual. Training activities for these studies will be suspended.
- Participant accrual into all studies will be suspended (screening and enrollment screens for all studies have been closed by the Data Management Center).
- For most IMPAACT studies, follow-up of participants should continue — to the extent possible and in accordance with relevant government and site-specific institutional policies — with emphasis on safety monitoring and ensuring access to treatment regimens for participants living with HIV. The MOG will follow-up with protocol chairs regarding more detailed guidance and contingency planning relevant to each study. Additional guidance for sites will be provided through each protocol team.
- Shipments of study specimens to the IMPAACT repositories and designated testing laboratories will be suspended (all stored specimens will be retained on-site).

We understand that the measures outlined above will have an economic impact on sites and are working to ensure that bridge funding can be made available as needed. We also encourage you to actively communicate with protocol teams for any protocol- or participant-specific questions and with your DAIDS program officer or Westat site representative regarding any broader site-specific issues.

We will continue to monitor the situation closely and will provide updates as needed. Please contact us with any questions and concerns. We are all in this together and look forward to the time that our usual activities can be safely resumed. 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 over the next few challenging months and beyond!

Sincerely,

A handwritten signature in black ink, appearing to read 'Sharon Nachman'.

Sharon Nachman, MD
IMPAACT Network Chair

A handwritten signature in black ink, appearing to read 'James McIntyre'.

James McIntyre, MD
IMPAACT Network Vice Chair