

DATE: March 18, 2020

- TO: AIDS Clinical Trials Group (ACTG) Colleagues
- FROM: Dr. Judith Currier, ACTG Principal Investigator and Chair, ACTG Executive Committee Dr. Joseph Eron, Jr., ACTG Co-PI, Chair, Scientific Agenda Steering Committee
- SUBJ: ACTG Guidance: Response to COVID-19 Pandemic

As you know, the COVID-19 pandemic is evolving rapidly, creating a significant public health risk that has disrupted many aspects of daily life worldwide. In response to this situation, which is likely to persist, the ACTG Network Leadership is issuing the following guidance, which we believe will protect the health of our participants and the ACTG research community and support the best outcomes for our research program:

- Enrollment into all open studies will halt until further notice. The ACTG Data Management Center will close each study's enrollment screens. Participants currently in screening should NOT be enrolled, except for entry to the three studies listed below, provided that each site's IRB will permit this exception:
 - Household members in A5300B/I2003B/PHOENIx who are from a household where one household member has already been enrolled
 - Individuals currently in screening for A5375 ("Optimize LNG EC") and A5312 ("High-Dose Isoniazid")
- No NEW ACTG study will open to accrual until further notice.
- Site activations (U.S. and non-U.S.) should continue as usual. Upon resumption of enrollment into ACTG studies, these sites' enrollment screens will be enabled as usual.
- Site Community Advisory Boards (CABs) should suspend all in-person meetings at this time. Virtual meetings are encouraged.
- Specimen shipments will cease. (See the attached memorandum distributed on 3/17/20.)

Sites with participants on studies will hear from the study teams in the coming days with instructions about other implementation changes regarding virtual visits. In addition, sites should notify their Division of AIDS (DAIDS) Program Officer (PO) and study teams about any site-specific study implementation changes. No DAIDS site monitoring visits will occur until further notice.

We encourage you to direct study-related questions to the relevant protocol team. Other questions should be addressed to the network leadership or the DAIDS PO.

All guidance related to COVID-19 will be posted to the ACTG member website (<u>https://member.mis.s-3.net/</u>). We are monitoring the situation closely and will update you as developments dictate.

Thank you for all of your efforts to protect our research participants, our research staff, and yourselves during these unprecedented times.

Attachment: ACTG Specimen Shipments memorandum, dated March 17, 2020

cc: Dr. Ian Sanne Ms. Bola Adedeji Dr. Peter Kim Dr. Akinlolu Ojumu

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