

## Section 17. COVID-19 Measures

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### 17.1 Overview of Section 17

This section provides a brief overview of recommendations for trial conduct during the COVID Pandemic.

### 17.2 Conducting visits

These recommendations are made with the goal of ensuring both participant and staff safety and respecting the public health recommendations to minimize disease transmission.

Sites may choose to provide ICFs to participants ahead of visits to minimize time on site and participant/ site contact and to allow participants to read, make notes, discuss with family and friends if needed. Prior to implementing such a plan, sites should develop an SOP detailing the procedures and methods for the process which should also be approved by applicable ethics/ regulatory authorities. The site may also contact the potential participant telephonically to discuss the forms and any questions she may have. When contacting the participant, the site must confirm the participant identity (name, date of birth, and potentially information known to the site and the participant but not a 3rd party) and document the conversation in chart notes. This does not mean that the consent process may be entirely remote. Sites that are able may deliver, mail, WhatsApp, or share by means of other communication platforms the Informed Consent(s) to participants prior to a study visit so that they may review the form. Given that the consent form is unsigned, it gives participants an opportunity to discuss with her partner or family prior to signing and to identify any potential barriers to consent prior to participation. When the participant presents to the clinic for a visit, staff will offer a general overview of the consent form and answer any questions and sites may then obtain the wet signature and assessment of understanding. In some cases, a complete review may be necessary.

Note: Make sure that any study materials (including blank informed consents and flyers) are shared without risk of harm.

- Sites can always counsel participants to think about who they want to talk to share information with ahead of time, and if the participant indicates that she is concerned about her partner then a secure channel for communication should be identified.
- The issues of security with sending blank informed consents via WhatsApp or other communication platforms apply to participants that are already enrolled and that are re- consenting.

Follow-up visits should continue to ensure safety of the participants in alignment with local guidance and protocol where possible.

1. **In the event that CRS operations are diminished or suspended entirely, and where conduct of study visits is not possible either because of staffing or operational concerns, please note the following:**

**For participants on maintenance doses of CAB LA:** Injections may be lengthened to 12 weeks (ie the full visit window) in the event of prolonged lockdowns or ongoing COVID disruption. Every effort should be made to confirm participant identity prior to initiating data collection. For example, information like name, date of birth, and responses about clinic or study information might be considered reasonable ways to confirm participant identity. Participants may be reimbursed for telephonic data collection, given that there may be costs to them associated with phone calls, and this is acceptable to the local IRB/REC. If for some reason participants cannot receive study product, they are advised to take additional measures to prevent HIV infection and exposure by all means available until they can return to study site. If they use non-study provided open-label PrEP during this period they should be encouraged to keep a log of dates of use should they use this option.

**For participants on TDF/FTC:** Participants should continue on daily unblinded oral product. Where participants cannot report for quarterly visits, participants should continue study product and where possible sites should explore delivery of product directly to participants from site investigational pharmacies. The DAIDS guidelines for shipping product should be followed. If not feasible, participants should be counselled to use other available means to protect themselves against HIV exposure and infection and pregnancy prevention until they are able to return to study participation. IoR can use their judgement about ongoing dispensation of oral product in these extraordinary circumstances without routine HIV and creatinine testing, based on known previous renal function, risk and adherence. Self-testing for HIV may also be useful in this setting if practical. The same guidance would apply to pregnant participants.

**For annual follow up if applicable:** Annual visits should be delayed until study conduct can be resumed at the site.

2. **PLEASE NOTE:** Notify the protocol chairs, LOC, LC, SDMC and DAIDS as soon as possible of any updates to your site-specific plan. Please note that additional guidance was issued to CTU PIs and CRS leaders regarding considerations for visits during this extraordinary time by DAIDS.

Sites should consider procedures for symptom screening and isolation of suspected cases and linkage to testing based on national guidelines.

### **173 Incomplete or Missed Visits**

Any procedures that cannot be conducted per protocol should be recorded as protocol deviations per guidance in SSP Section 3, and per the Data Communique #8. Follow Data Communique #8 Dated 2 April 2020 for instructions on Missed Visits, Telephonic Visits, Partial Visits, Product Holds or Discontinuations, Open Label Truvada Administration and guidance on Pill Count/ Dissemination CRFs ([https://www.hptn.org/sites/default/files/inline-files/HPTN084\\_Data\\_Communique\\_8\\_20200402.pdf](https://www.hptn.org/sites/default/files/inline-files/HPTN084_Data_Communique_8_20200402.pdf)).

In addition, teams should continue to send queries to the CMC. Where possible CMC queries should be sent ahead of anticipated participant visits to ensure sufficient response time from the CMC. Where queries are sent on the same day and where an immediate response is not possible, investigators may use their discretion regarding the dispensing of study product after assessment of safety parameters.

### **174 Covid-19 vaccinations**

If a participant has been vaccinated please document this on the ConMeds CRF. If the vaccine is part of a clinical trial also contact the HPTN 084 CMC when you are made aware in order to manage participant/ trial burden.