## Section 17. COVID-19 Measures

<table>
<thead>
<tr>
<th>17.1</th>
<th>Overview of Section 17</th>
<th>17-1</th>
</tr>
</thead>
<tbody>
<tr>
<td>17.2</td>
<td>Conducting visits</td>
<td>17-1</td>
</tr>
<tr>
<td>17.3</td>
<td>Incomplete or Missed Visits</td>
<td>17-3</td>
</tr>
<tr>
<td>17.4</td>
<td>Covid-19 vaccinations</td>
<td>17-3</td>
</tr>
</tbody>
</table>

### 17.1 Overview of Section 17

This section provides a brief overview of recommendations for trial conduct during the COVID Pandemic. These useful resources continue to be posted to the HPTN 084 page: [https://www.hptn.org/research/studies/hptn084](https://www.hptn.org/research/studies/hptn084)

- DAIDS COVID-19 Guidance
- The COVID-19 Risk Communication Package For Healthcare Facilities
- WHO guidance for the rational use of personal protective equipment (PPE) for coronavirus disease (COVID-19) March 2020
- WHO guidance on getting your workplace ready for COVID-19
- WHO Q&A on COVID-19 and masks
- CDC Strategies to Optimize the Supply of PPE and Equipment


### 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 Informed Consent Forms 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 
cconcerns, please note the following:**

**For participants in Step 4:** Sufficient study products (up to a 90-day supply) should 
be provided to cover 12 weeks in the event that lockdowns continue. 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 step 5 visit schedule:** 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.

17.3 **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).

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.

17.4 **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.