

Section 12. Data Communiqués

For HPTN 052, SCHARP will be using “Data Communiqués” to document and communicate data decision and procedures that are made or revised during the study. By using Data Communiqués, SCHARP avoids having to re-distribute a revised version of the Data Collection section of this SSP every time a form completion clarification or revision is made.

Data Communiqués are considered official study documentation. As such, each time a Communiqué is sent (via email), please circulate it among relevant staff for their review, print the Communiqué, and place it in this section of each 052 SSP binder in your possession. Consider each Communiqué an official part of the SSP.

Each Data Communiqué sent will consist of 3 sections: A Reminders section, used to remind sites of specific data collection or forms completion procedures; a Clarification section, used to clarify data collection or form completion procedures; and an Updates section, used to communicate when an updated version of a form is being issued or to notify the sites that an updated version of the forms instructions is about to be distributed (for example).

Note that a “Data Communiqué” does not request specific actions or corrections to a particular participant’s data – it is just a listing of general items to keep in mind when performing data collection for the study.