

## **Section 14. SCHARP Data Communiques**

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For HPTN 059, SCHARP will use “Data Communiques” to document and communicate data decisions and procedures that are made or revised during the study. By using Data Communiques, 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 Communiques are considered official study documentation. As such, each time a Data Communique is sent (via email), please circulate it among relevant staff for their review, print the Data Communique, and place it in this section of each HPTN 059 SSP binder in your possession. Consider each Data Communique an official part of the SSP.

Each Data Communique sent will consist of three 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 Communique” 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.