



## Protocol HVTN XXX Documentation of Training

CRS Site Name \_\_\_\_\_

Protocol-Specific Training Sessions	Presenter	Approx. Time	Session Description	Expected Audience <sup>1</sup> (See "By CRS Task" box below)
Protocol Overview	[CHAIR]		<i>Review of Protocol HVTN XXX</i>	1 through 16
Pharmacy Procedures	[DAIDS Pharmacist]		<i>Review of the HVTN XXX Pharmacy Procedures</i>	1-2, 12-13
Safety Monitoring	[CASA]		<i>Review of clinical and safety assessments, safety pause rules and reactogenicity-related issues</i>	1-2, 8-9, 13-14
Study Materials	[PM]		<i>Review of the HVTN XXX study materials, new &amp; changed CRFs, highlights from the SSP</i>	1-2, 4-16
Pharmacist-specific procedures	[DAIDS Pharmacist]		<i>Review of the HVTN XXX Pharmacy Procedures that are specific to the Pharmacist staff</i>	12
Cross-Protocol Training Sessions	Presenter	Approx. Time	Session Description	Expected Audience (See "By CRS Task" box below)
Specimen Collection Checklist	Cristine Cooper	5 min	<i>Review of the Specimen Collection Checklist/Requisition forms</i>	1-2, 10-11
DataFAX, Data Management System	Claire Chapdu	26 min	<i>Overview of DataFAX Form Completion</i>	1-2, 8, 16
DataFAX Quality Control Reports	Susan Tracey-Waisanen	6 min	<i>Overview and Process of QC Reports</i>	1-2, 8, 16
Safety Reporting Essentials for HVTN Studies	Molly Swenson	20 min	<i>Overview of reactogenicity reporting, AE/SAE/EAE reporting, and clinical/coding queries</i>	1-2, 8-9, 13-14
Randomization Procedures	Huguette Redinger	15 min	<i>Review of randomization system, visit schedule utility &amp; query utility for summarizing activity</i>	1-2, 7, 12
Rounding and Recording Lab Values and Assigning Severity Grades	Pat Farrell	10 min	<i>Review of HVTN Rounding Procedures</i>	1-2, 5, 8-9, 14
Visit Scheduling Tool	Huguette Redinger	10 min	<i>SCHARP Visit Scheduler Tool (overview)</i>	1-2, 7
Visit Windows-Interim Visits	Shelly Mahilum	10 min	<i>Review of Visit Windows and Interim Visits</i>	1-2, 7-10, 13, 16
<b>Q&amp;A</b>	<b>Multiple presenters</b>		<b>Questions&amp; answers covering the HVTN XXX Protocol and study materials. Live on [insert date]. Minutes available on the HVTN XXX webpage</b>	<b>1 through 16</b>

**Expected Audience: By CRS Task** <sup>1</sup> Additional staff to be added at site's discretion

1. Coordinates clinic	7. Randomizes participants	12. Performs pharmacy-specific procedures
2. Provides back-up to Clinic Coordinator	8. Completes DataFAX forms	13. Administers vaccine
3. Recruits participants	9. Clinically assesses participants	14. Assesses reactogenicity
4. Reviews and/or obtains informed consent	10. Collects specimens	15. Performs regulatory submission
5. Verifies eligibility	11. Performs shipping and/or lab-specific procedures	16. Manages QCs
6. Counsels and/or interviews participants		

If applicable, mark checkbox:

SCHARP staff performed an in-person training of our site staff members.

I assure that staff critical to the implementation of this protocol have received appropriate training. I will maintain the protocol documentation of training (p. 2) and update in our site's regulatory files as necessary.

\_\_\_\_\_  
Name of PI or designee

\_\_\_\_\_  
Signature of PI or designee

\_\_\_\_/\_\_\_\_/\_\_\_\_  
Date

Please submit to HVTN Regulatory Affairs by e-mail (vtn.activation@hvtn.org.)

If you are unable to email, you may fax to 206-667-5699.

