



Protocol HVTN XXX Documentation of Training

CRS Name _____

Protocol-Specific Training Sessions	Presenter	Approx. Time	Session Description	Expected Audience (See "By CRS Task" box below)
Protocol Overview	[Chair]		<i>Review of Protocol HVTN XXX</i>	1 through 12
Study Materials	[PM]		<i>Review of the HVTN XXX study materials, new & changed CRFs, highlights from the SSP</i>	1-2, 4-12
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, 9-10
DataFax, Data Management System	Claire Chapdu	26 min	<i>Overview of DataFax Form Completion</i>	1-2, 7, 12
DataFax Quality Control Reports	Susan Tracey-Waisanen	6 min	<i>Overview and Process of QC Reports</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, 7-8
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, 7-9, 12
Q&A	Multiple presenters		Questions & answers covering the HVTN XXX Protocol and study materials. Live on [insert date]. Minutes available on the HVTN XXX webpage	1 through 12

Expected Audience: By CRS Task

1. Coordinates clinic	5. Verifies eligibility	9. Collects specimens
2. Provides back-up to clinic coordinator	6. Counsels and/or interviews participants	10. Performs shipping and/or lab-specific procedures
3. Recruits participants	7. Completes DataFax forms	11. Performs regulatory submissions
4. Reviews and/or obtains informed consent	8. Clinically assesses participants	12. Manages QCs

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@hvtm.org.)
If you are unable to email, you may fax to 206-667-5699.**

