

Documentation of Training

HVTN Ops Day

November 16, 2009

Documentation of Training

Purpose of presentation

- Background
- How to use
- Review changes to form
- Obtain feedback

Documentation of Training

Background

- Not a new form
- Provides guidance on what training is required and available for sites
- Required for site activation

Documentation of Training



Protocol HVTN XXX Documentation of Training

CRS Site Name _____

Protocol-Specific Training Sessions	Presenter	Approx. Time	Session Description	(S)
Protocol Overview	[HAF]		Review of Protocol HVTN XXX	
Pharmacy Procedures	[DAIDS Pharmacists]		Review of the HVTN XXX Pharmacy Procedures	
Safety Monitoring	[ASG]		Review of clinical and safety assessments, safety pause rules and reactivity-related issues	
Study Materials	[PM]		Review of the HVTN XXX study materials, new & changed CRFs, highlights from the SSP	
Pharmacy-specific procedures	[DAIDS Pharmacists]		Review of the HVTN XXX Pharmacy Procedures that are specific to the Pharmacists staff	
Cross-Protocol Training Sessions	Presenter	Approx. Time	Session Description	(S)
Specimen Collection Checklist	Cristine Cooper	5 min	Review of the Specimen Collection Checklist/Requestion forms	
DataFax, Data Management System	Claire Clapdt	25 min	Overview of DataFax/Form Completion	
DataFax Quality Control Reports	Susan Tracey-Walkara	6 min	Overview and Process of QC Reports	
Safety Reporting Essentials for HVTN Studies	Molly Swanson	20	Overview of reactivity reporting, ADR/SAE reporting, and clinical coding queries	
Randomization Procedures	Huguette Rediger	15 min	Review of randomization system, visit schedule utility & query utility for summarizing activity	
Rounding and Recording Lab Values and Assigning Severity Grades	Pat Farrell	10 min	Review of HVTN Rounding Procedures	
Visit Scheduler Tool	Huguette Rediger	10 min	SCHARP Visit Scheduler Tool (overview)	
Visit Windows-Interim Visits	Stella Maklith	10 min	Review of visit windows and interim visits	
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	

Expected Audience: By CRS Task

1. Coordinates clinic	7. Randomizes participants	12. Performs pham
2. Provides back-up to Clinic Coordinator	8. Completes DataFax forms	13. Admits to lab
3. Recruits participants	9. Clinically assesses participants	14. Assesses react
4. Reviews and/or obtains informed consent	10. Collects specimens	15. Performs regula
5. Verifies eligibility	11. Performs skipping and/or lab-specific procedures	16. Manages QCs
6. Counsel 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 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

Please submit to HVTN Regulatory Affairs by e-mail (vtn_activation@hvtm.org.)

HVTN Protocol Template and tool_PM Draft Documentation of Training vctms_071810_CG.doc



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	[Clalf]		Review of Protocol HVTN XXX	1 through 12
Study Materials	[PM]		Review of the HVTN XXX study materials, new & changed CRFs, highlights from the SSP	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	Review of the Specimen Collection Checklist/Requestion forms	1-2, 9-10
DataFax, Data Management System	Claire Clapdt	25 min	Overview of DataFax/Form Completion	1-2, 7, 12
DataFax Quality Control Reports	Susan Tracey-Walkara	6 min	Overview and Process of QC Reports	1-2, 7, 12
Rounding and Recording Lab Values and Assigning Severity Grades	Pat Farrell	10 min	Review of HVTN Rounding Procedures	1-2, 5, 7-8
Visit Scheduler Tool	Huguette Rediger	10 min	SCHARP Visit Scheduler Tool (overview)	1-2, 7
Visit Windows-Interim Visits	Stella Maklith	10 min	Review of Visit Windows and Interim Visits	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. Counsel and/or interviews participants	10. Performs skipping 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.

Documentation of Training

Background, cont.

- Contains Protocol-specific and Cross-protocol training sessions
- Posted as .pdf on protocol-specific webpage
- Lists “Expected Audience” by CRS task

Documentation of Training

How to use

- View protocol-specific website with Documentation of Training
- Make sure staff have covered all training sessions posted on website and listed in document
- Fill out and submit PI signature page to HVTN Regulatory Affairs
- If a new training is posted after study opening, a new document will not be distributed

Documentation of Training

Review Changes to Form

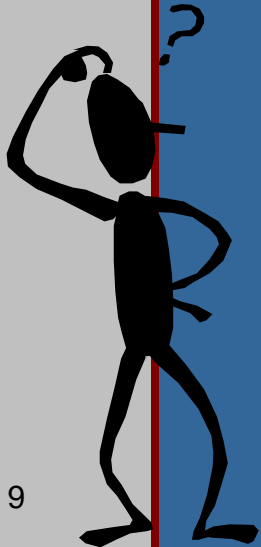
- Refined the “Expected Audience” to be more in line with Staff Delegation Form
- Created a vaccine and non-vaccine version
- Added additional trainings, e.g.
 - Safety Reporting Essentials for HVTN Studies
 - Visit Scheduling Tool

Topics of Discussion

- Are “expected audiences” appropriate?
- Are there other recorded trainings that SCHARP can provide?

QUESTIONS?

Contact your **SCHARP** Project Manager



Statistical Center for
HIV/AIDS Research & Prevention
SCHARP