



HPTN Study Operations Report

January 2011

PTN Executive Summary Report
12 January 2011
Enrollment Summary

Protocol	Site	Date of First Enrollment	Target Number	Total Enrolled	% Target Enrollment	Months of Enrollment	Cumulative Enrollment Per Month	% Enrollment Period
046 V2 (Mothers)	Uganda – Mulago Hospital	08Feb2007	190	190	100%	8.2	23.2	completed
	Zimbabwe – Harare/Chitungwiza	09Mar2007	157	157	100%	7.8	20.1	completed
	Total		347	347	100%	8.8	39.4	
046 V2 (Infants)	Uganda – Mulago Hospital	08Feb2007	190	193	102%	8.2	23.5	completed
	Zimbabwe – Harare/Chitungwiza	09Mar2007	157	157	100%	7.8	20.1	completed
	Total		347	350	101%	8.8	39.8	
046 V3 (Mothers)	South Africa – Durban – Prince Mshiyeni Hospital	22Jul2008	400	408	102%	18	22.7	completed
	Tanzania – Dar Es Salaam	28Jan2009	270	218	81%	10	21.8	closed
	Uganda – Mulago Hospital	23Jun2008	500	545	109%	19.2	28.4	completed
	Zimbabwe – Harare/Chitungwiza	14May2008	500	507	101%	20.5	24.7	completed
	Total		1670	1678	100%	20.5	81.9	
046 V3 (Infants)	South Africa – Durban – Prince Mshiyeni Hospital	22Jul2008	400	409	102%	18	22.7	completed
	Tanzania – Dar Es Salaam	28Jan2009	270	219	81%	10	21.9	closed
	Uganda – Mulago Hospital	23Jun2008	500	562	112%	19.2	29.3	completed
	Zimbabwe – Harare/Chitungwiza	14May2008	500	510	102%	20.5	24.9	completed
	Total		1670	1700	102%	20.5	82.9	
052 Run-in (Indexes)	US – Boston – Fenway Community Health Center	24Oct2005	6	2	33%	11.5	0.2	closed
	Brazil – Porto Alegre	30Jan2006	5	5	100%	3.3	1.5	completed
	Brazil – Rio de Janeiro	22Sep2005	15	15	100%	2.2	6.8	completed
	India – Chennai – YRGCare	10Nov2005	10	10	100%	1.3	7.7	completed
	India – Pune	01Jul2005	10	10	100%	2.2	4.5	completed
	Malawi – Blantyre – Queen Elizabeth Central	25Aug2005	10	10	100%	6.9	1.4	completed
	Malawi – Lilongwe – Lilongwe Central Hospital	12Apr2005	10	10	100%	1.2	8.3	completed
	Thailand – Chiang Mai	24Jun2005	10	10	100%	2.3	4.3	completed
	Zimbabwe – Harare – Parirenyatwa Hospital	09Jan2006	10	10	100%	2.4	4.2	completed
Total		86	82	95%	18	4.6		
052 Run-in (Partners)	US – Boston – Fenway Community Health Center	24Oct2005	6	2	33%	11.5	0.2	closed
	Brazil – Porto Alegre	30Jan2006	5	5	100%	3.3	1.5	completed
	Brazil – Rio de Janeiro	22Sep2005	15	15	100%	2.2	6.8	completed

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	India – Chennai – YRGCare	10Nov2005	10	10	100%	1.3	7.7	completed
	India – Pune	01Jul2005	10	10	100%	2.2	4.5	completed
	Malawi – Blantyre – Queen Elizabeth Central	25Aug2005	10	11	110%	6.9	1.6	completed
	Malawi – Lilongwe – Lilongwe Central Hospital	12Apr2005	10	10	100%	1.2	8.3	completed
	Thailand – Chiang Mai	24Jun2005	10	10	100%	2.3	4.3	completed
	Zimbabwe – Harare – Parirenyatwa Hospital	09Jan2006	10	10	100%	2.4	4.2	completed
	Total		86	83	97%	18	4.6	
052 Full Study (Indexes)	Botswana – Gaborone	16Apr2009	74	77	104%	12.1	6.4	completed
	Brazil – Porto Alegre	26Nov2007	84	85	101%	28.9	2.9	completed
	Brazil – Rio de Janeiro	14Nov2007	168	171	102%	29.4	5.8	completed
	India – Chennai – YRGCare	05Jul2007	240	240	100%	29.8	8.1	completed
	India – Pune	28Jun2007	163	165	101%	33.6	4.9	completed
	Kenya – Kisumu	03Nov2009	59	60	102%	6	10	completed
	Malawi – Blantyre – Queen Elizabeth Central	16Jan2008	219	220	100%	27.3	8.1	completed
	Malawi – Lilongwe – Lilongwe Central Hospital	06Dec2007	241	241	100%	26.5	9.1	completed
	South Africa – Johannesburg – Witwatersrand	20May2008	44	46	105%	23.4	2	completed
	South Africa – Soweto	11Jun2009	49	50	102%	10.2	4.9	completed
	Thailand – Chiang Mai	11Oct2007	98	96	98%	30.1	3.2	closed
	Zimbabwe – Harare – Parirenyatwa Hospital	05Nov2007	229	230	100%	29.7	7.7	completed
	Total		1668	1681	101%	34.7	48.4	
052 Full Study (Partners)	Botswana – Gaborone	16Apr2009	74	77	104%	12.1	6.4	completed
	Brazil – Porto Alegre	26Nov2007	84	88	105%	28.9	3	completed
	Brazil – Rio de Janeiro	14Nov2007	168	174	104%	29.4	5.9	completed
	India – Chennai – YRGCare	05Jul2007	240	240	100%	29.8	8.1	completed
	India – Pune	28Jun2007	163	165	101%	33.6	4.9	completed
	Kenya – Kisumu	03Nov2009	59	60	102%	6	10	completed
	Malawi – Blantyre – Queen Elizabeth Central	16Jan2008	219	220	100%	27.3	8.1	completed
	Malawi – Lilongwe – Lilongwe Central Hospital	06Dec2007	241	245	102%	26.5	9.2	completed
	South Africa – Johannesburg – Witwatersrand	20May2008	44	46	105%	23.4	2	completed
	South Africa – Soweto	11Jun2009	40	50	125%	10.2	4.9	completed
	Thailand – Chiang Mai	11Oct2007	98	97	99%	30.1	3.2	closed

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	Zimbabwe – Harare – Parirenyatwa Hospital	05Nov2007	229	230	100%	29.7	7.7	completed
	Total		1668	1692	101%	34.7	48.8	
057 (Mothers)	Brazil – Belo Horizonte	08Aug2007	12	12	100%	41.8	0.3	109%
	Brazil – Porto Alegre – Conceicao	15Jun2008	8	10	125%	31.4	0.3	112%
	Brazil – Porto Alegre – Santa Casa	19Sep2007	15	15	100%	40.4	0.4	109%
	Brazil – Rio de Janeiro	17Apr2008	8	13	163%	33.3	0.4	112%
	Malawi – Blantyre – Queen Elizabeth Central	26Dec2006	71	72	101%	43.4	1.7	completed
	Total		114	122	107%	49.3	2.5	
057 (Infants)	Brazil – Belo Horizonte	08Aug2007	12	12	100%	41.8	0.3	109%
	Brazil – Porto Alegre – Conceicao	15Jun2008	8	10	125%	31.4	0.3	112%
	Brazil – Porto Alegre – Santa Casa	19Sep2007	15	15	100%	40.4	0.4	109%
	Brazil – Rio de Janeiro	17Apr2008	8	13	163%	33.3	0.4	112%
	Malawi – Blantyre – Queen Elizabeth Central	27Dec2006	71	72	101%	43.4	1.7	completed
	Total		114	122	107%	49.2	2.5	
058	China – Guangxi – Heng County	24Dec2008	405	311	77%	25	12.4	68%
	China – Nanning	19May2010	350	76	22%	7.9	9.6	40%
	China – Xinjiang	23Dec2008	495	339	68%	25	13.6	68%
	Thailand – Chiang Mai University	30May2007	202	202	100%	28.7	7	completed
	Total		1500	928	62%	44.1	21	
061	US – Atlanta	26Feb2010	201	116	58%	7	16.6	closed
	US – Boston	17Jul2009	403	237	59%	15.3	15.5	closed
	US – Decatur	16Sep2009	202	184	91%	12.2	15.1	closed
	US – Los Angeles	30Sep2009	403	283	70%	12.3	23	closed
	US – NY – Harlem Prevention Center	08Jan2010	201	154	77%	6.3	24.4	closed
	US – NY – New York Blood Center	01Oct2009	202	156	77%	10.7	14.6	closed
	US – San Francisco	13Aug2009	403	204	51%	13.6	15	closed
	US – Washington DC	28Jul2009	403	227	56%	14.2	16	closed
	Total		2418	1561	65%	15.3	102	
062	Malawi – Lilongwe – Lilongwe Central Hospital	26Apr2010	46	16	35%	8.7	1.8	

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	Total		46	16	35%	8.7	1.8	
063	Brazil – Rio de Janeiro	–	300	–	–	0	–	pending
	Thailand – Chiang Mai	01Apr2010	300	61	20%	9.5	6.4	pending
	Zambia – Lusaka – Matero Clinic	–	200	–	–	0	–	pending
	Total		800	61	8%	9.5	6.4	
064 (Women)	US – Atlanta	22Oct2009	200	215	108%	7	30.7	completed
	US – Baltimore	05Aug2009	200	210	105%	8.7	24.1	completed
	US – Chapel Hill	26May2009	200	210	105%	8.7	24.1	completed
	US – Decatur	27Aug2009	200	211	106%	11.9	17.7	completed
	US – NY – Bronx–Lebanon Hospital Center	16Jun2009	200	210	105%	8.4	25	completed
	US – NY – Harlem Prevention Center	26Oct2009	200	210	105%	7.4	28.4	completed
	US – Newark	05Jun2009	400	420	105%	10.5	40	completed
	US – Raleigh	11Aug2009	200	210	105%	5.7	36.8	completed
	US – Washington DC	17Jun2009	200	211	106%	10.3	20.5	completed
	Total			2000	2107	105%	15	140.5
064 (Men)	US – Decatur	10Mar2010	30	43	143%	4.9	8.8	completed
	US – NY – Bronx–Lebanon Hospital Center	30Sep2009	30	54	180%	6.7	8.1	completed
	US – Raleigh	29Apr2010	30	37	123%	3.2	11.6	completed
	US – Washington DC	02Apr2010	30	40	133%	2.8	14.3	completed
	Total			120	174	145%	10.3	16.9

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Retention Summary

Protocol	Site	Total Enrolled	Expected Visits	Completed Visits	Protocol Expectations	Retention Rate	Protocol Expected Standard
046 V2 (Mothers)	Uganda – Mulago Hospital	190	1140	1057	1071	93%	94%
	Zimbabwe – Harare/Chitungwiza	157	942	821	885	87%	94%
	Total	347	2082	1878	1956	90%	94%
046 V2 (Infants)	Uganda – Mulago Hospital	193	2123	1997	2015	94%	95%
	Zimbabwe – Harare/Chitungwiza	157	1727	1611	1639	93%	95%
	Total	350	3850	3608	3654	94%	95%
046 V3 (Mothers)	South Africa – Durban – Prince Mshiyeni Hospital	408	2304	1993	2176	87%	94%
	Tanzania – Dar Es Salaam	218	1170	1038	1111	89%	95%
	Uganda – Mulago Hospital	545	3021	2851	2858	94%	95%
	Zimbabwe – Harare/Chitungwiza	507	2849	2627	2692	92%	94%
	Total	1678	9344	8509	8837	91%	95%
046 V3 (Infants)	South Africa – Durban – Prince Mshiyeni Hospital	409	4354	4047	4145	93%	95%
	Tanzania – Dar Es Salaam	219	2271	2066	2168	91%	95%
	Uganda – Mulago Hospital	562	5930	5764	5649	97%	95%
	Zimbabwe – Harare/Chitungwiza	510	5417	5108	5157	94%	95%
	Total	1700	17972	16985	17119	95%	95%
052 Combined (Indexes)	Botswana – Gaborone	77	487	476	482	98%	99%
	Brazil – Porto Alegre	90	911	894	891	98%	98%
	Brazil – Rio de Janeiro	184	2105	2065	2052	98%	97%
	India – Chennai – YRGCare	250	2742	2493	2677	91%	98%
	India – Pune	175	1914	1893	1866	99%	97%
	Kenya – Kisumu	60	311	303	309	97%	99%
	Malawi – Blantyre – Queen Elizabeth Central	230	2052	1931	2012	94%	98%
	Malawi – Lilongwe – Lilongwe Central Hospital	251	2382	2220	2332	93%	98%
	South Africa – Johannesburg – Witwatersrand	46	381	364	375	96%	98%
	South Africa – Soweto	50	273	260	271	95%	99%
	Thailand – Chiang Mai	106	1176	1163	1145	99%	97%
	Zimbabwe – Harare – Parirenyatwa Hospital	240	2170	2056	2127	95%	98%
	Total	1759	16904	16118	16537	95%	98%

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Protocol	Site	Total Enrolled	Expected Visits	Completed Visits	Protocol Expectations	Retention Rate	Protocol Expected Standard	
052 Combined (Partners)	Botswana – Gabarone	77	487	456	482	94%	99%	
	Brazil – Porto Alegre	93	911	859	891	94%	98%	
	Brazil – Rio de Janeiro	187	2105	1760	2052	84%	97%	
	India – Chennai – YRGCare	250	2742	2291	2677	84%	98%	
	India – Pune	175	1914	1851	1866	97%	97%	
	Kenya – Kisumu	60	311	301	309	97%	99%	
	Malawi – Blantyre – Queen Elizabeth Central	231	2052	1705	2012	83%	98%	
	Malawi – Lilongwe – Lilongwe Central Hospital	255	2382	1981	2332	83%	98%	
	South Africa – Johannesburg – Witwatersrand	46	381	343	375	90%	98%	
	South Africa – Soweto	50	273	251	271	92%	99%	
	Thailand – Chiang Mai	107	1176	1066	1145	91%	97%	
	Zimbabwe – Harare – Parirenyatwa Hospital	240	2170	1842	2127	85%	98%	
	Total		1771	16904	14706	16537	87%	98%
	057 (Mothers)	Brazil – Belo Horizonte	12	62	57	60	92%	97%
Brazil – Porto Alegre – Conceicao		10	49	44	48	90%	98%	
Brazil – Porto Alegre – Santa Casa		15	83	79	80	95%	97%	
Brazil – Rio de Janeiro		13	66	60	64	91%	97%	
Malawi – Blantyre – Queen Elizabeth Central		72	409	382	397	93%	97%	
Total			122	669	622	649	93%	97%
057 (Infants)	Brazil – Belo Horizonte	12	70	65	68	93%	97%	
	Brazil – Porto Alegre – Conceicao	10	54	49	52	91%	97%	
	Brazil – Porto Alegre – Santa Casa	15	96	92	92	96%	96%	
	Brazil – Rio de Janeiro	13	73	67	71	92%	97%	
	Malawi – Blantyre – Queen Elizabeth Central	72	465	433	448	93%	96%	
	Total		122	758	706	731	93%	96%
058	China – Guangxi – Heng County	311	505	409	460	81%	91%	
	China – Nanning	76	17	15	16	88%	94%	
	China – Xinjiang	339	592	484	537	82%	91%	
	Thailand – Chiang Mai University	202	752	668	655	89%	87%	
	Total		928	1866	1576	1668	84%	89%

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Protocol	Site	Total Enrolled	Expected Visits	Completed Visits	Protocol Expectations	Retention Rate	Protocol Expected Standard
061	US – Atlanta	116	61	47	58	77%	94%
	US – Boston	237	214	155	199	72%	93%
	US – Decatur	184	153	86	143	56%	94%
	US – Los Angeles	283	218	161	203	74%	93%
	US – NY – Harlem Prevention Center	154	143	131	135	92%	94%
	US – NY – New York Blood Center	156	144	112	135	78%	94%
	US – San Francisco	204	229	165	213	72%	93%
	US – Washington DC	227	198	157	185	79%	93%
	Total	1561	1360	1014	1270	75%	93%
062	Malawi – Lilongwe – Lilongwe Central Hospital	16	103	102	101	99%	98%
	Total	16	103	102	101	99%	98%
064 (Women)	US – Atlanta	215	238	215	224	90%	94%
	US – Baltimore	210	280	268	261	96%	93%
	US – Chapel Hill	210	313	285	291	91%	93%
	US – Decatur	211	205	182	192	89%	94%
	US – NY – Bronx–Lebanon Hospital Center	210	324	312	301	96%	93%
	US – NY – Harlem Prevention Center	210	244	220	229	90%	94%
	US – Newark	420	657	627	609	95%	93%
	US – Raleigh	210	374	333	345	89%	92%
	US – Washington DC	211	329	308	305	94%	93%
	Total	2107	2964	2750	2756	93%	93%

MEMORANDUM

DATE:	19 APR 2006
TO:	Study Operations Group
FROM:	Deborah Donnell
RE:	Summary of HPTN and MTN Enrollment and Recruitment
CC:	

These tables are based on the same data as the protocol specific enrollment and retention reports routinely sent out by SCHARP to each of the protocol teams.

Enrollment Summary

The Enrollment Summary describes the number of participants enrolled in each study based on the data received and entered at SCHARP. The report lists the date of **First Enrollment**, the **Target Number** of participants, and the **Total Number** enrolled to date for each site in each study. The percentage of target already enrolled is:

$$\text{Target Enrollment} = \frac{\text{Total Enrolled}}{\text{Target Number}}$$

As a guide to the sites' progress in enrollment, the percentage **Enrollment Period** elapsed is calculated - this is the elapsed proportion of the accrual period specified in the protocol.

Retention Summary

The Retention Summary is based on study visits. The table reports the number of **Expected Visits** for each site on each protocol - this is a calculation of all visits that should have occurred to date assuming no missed visits or loss to followup. **Completed Visits** are the number of these expected visits that have actually occurred (based on data received and entered at SCHARP). **Protocol Expectations** calculates the number of visits that should have occurred to date assuming the protocol specified acceptable loss to followup rate. Currently the report uses a retention standard of 10% annual loss to followup for HPTN035, HPTN037, and HPTN039 (i.e., Phase IIb and III trials), and 0% for the safety run-in phase of HPTN052.

Retention is simply the proportion of expected visits that have been completed:

$$\text{Retention} = \frac{\text{Completed}}{\text{Expected}}$$

As a guide for performance, the **Protocol Expected Standard** is calculated as the percentage of **Protocol Expected** visits that have occurred:

$$\text{Protocol Expected Standard} = \frac{\text{Protocol Expected}}{\text{Expected}}$$

The network evaluation committee has defined adequate performance as within 90% of the protocol expected standard.

Questions about this report may be directed to Deborah Donnell (deborah@scharp.org; (206) 667-5661).

HPTN Network Laboratory Update January 2011

I. HPTN 027

A. General Comments

1. Protocol Version - 2.0 dated 20th May 2005
2. SSP version – 2.0
3. Enrollment Status – Closed.
4. Date of last SMC call –29th September 2008
5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report: None
6. Lab related notes to file/deviations issued since preparation of SMC report: None
7. Miscellaneous
Results for Hepatitis B Surface Antibody, polio, tetanus and HIB have been submitted to SCHARP.

B. Site Specific

Kampala - There are many samples (around 1600) still stored at the JCRC. Plans to have these moved to MU-JHU IDI for permanent storage are underway.

C. Shipping / QA Status

All requested samples have been shipped and received by the HPTN NL

II. HPTN 046

A. General Comments

1. Protocol Version - 3.0 dated 26 Sept, 2007
2. SSP version – 5.0 dated 9th April 2008
3. Enrollment Status - closed
4. Date of last SMC call –May 17, 2010
5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report: None
6. Lab related notes to file/deviations issued since preparation of SMC report
 - a. Dar es Salaam – NTF issued May 19th describing the delay in the testing of one sample for DNA PCR – resolved. Dar es Salaam – Protocol Deviation form issued 26th May 2010 describing that a cell pellet storage was not requested by the clinic. BOTH PREVIOUSLY REPORTED June study ops
 - b. Dar es Salaam – Protocol Deviation form issued 26/May/2010 describing that plasma and DBS storage were not requested by the clinic. PREVIOUSLY REPORTED June study ops
 - c. Dar es Salaam – 8 Protocol Deviation forms received on 6.30.10 They describe the failure of the physician to request DBS or breast milk storage. Discovered during retrospective chart reviews. PREVIOUSLY REPORTED August study ops
 - d. UZ-UCSF – NTF issued Sep 22nd describing the movement of the DBS cards from the laboratory (temperature monitored) to a storage area for the laboratory. The lab recently started monitoring temperatures in the area. A list of PTIDs involved is still pending.
 - e. UZ-UCSF pending NTF regarding another power problem that affected the freezers at the off site location
 - f. UZ-UCSF –NTF regarding outage of WB kits in October, delaying resulting of 1 participant.

B. Site Specific

1. Harare - No new updates. Site is completing the LDMS reconciliations in a timely manner, submitted their QC for review, and submitted their inventory.
2. Kampala - No new updates. Site is completing the LDMS reconciliations in a timely manner, have not submitted their QC for review, and have not submitted their inventory.

3. Durban - No new updates. Site is completing the LDMS reconciliations in a timely manner, have not submitted their QC for review, and have not submitted their inventory.
4. Dar es Salaam - No new updates. Site is completing the LDMS reconciliations in a timely manner, have not submitted their QC for review, and have not submitted their inventory.

C. Shipping / QA Status

Further QA testing has been requested from the Uganda, Zimbabwe and Durban sites.

III. HPTN 052

A. General Comments

1. Protocol Version 3.0 dated 20 Nov 06
2. SSP version 1.6 dated 9 Jan 09
3. Enrollment Status. closed
4. Date of last SMC call – 12 Oct 10
5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report:
Lab Communique #4 issued October 18, 2010 clarifying Lab Communique #2 in regards to the required use of 2 rapid test kits for screening and partner follow up testing.
6. Lab-related notes to file/deviations issued since preparation of SMC report
 - a. HGNI – NTF regarding shortage of LN2 storage, sending samples for storage to IPEC. PREVIOUSLY REPORTED
 - b. HNSC – NTF regarding use of stored plasma for OraQuick validation PREVIOUSLY REPORTED
 - c. HNSC – NTF regarding switch from FDA approved EIA kits for partner screening to use of two rapid tests. PREVIOUSLY REPORTED
 - d. UZ-UCSF – NTF regarding outage of WB kits in October, delaying resulting of 1 partner sample. PREVIOUSLY REPORTED
 - e. UZ-UCSF – NTF regarding another power problem that affected the freezers at the off site location. PREVIOUSLY REPORTED
 - f. HGNI – NTF regarding the validation of the Abbott Determine and Oraquick tests. PREVIOUSLY REPORTED
 - g. UZ-UCSF – Protocol deviation regarding no WB testing done during screening of the index cases. PREVIOUSLY REPORTED
 - h. IPEC – NTF regarding use of back up lab for CD4 testing. PREVIOUSLY REPORTED
 - i. HGNI and IPEC – Viral load testing delay due to kit outage
 - j. IPEC – NTF regarding missing GUD swab found during chart review
 - k. NARI – NTF regarding switch to IQA approved FBS
 - l. Botswana – NTF regarding no plasma storage available on one participant in October.
7. Miscellaneous
The NL is continuing to work on the QA activity regarding partner seroconversions, genotyping and ARV testing.

B. Site Specific

1. Pune/NARI – The site has proposed a new site and new timeline has been submitted to DCLOT. The site has prepared the validation documents. Site has finalized the validation of the back-up instrument and is working on finalizing other validation documents. Have submitted their LDMS reconciliations, have not submitted their QC for review, but have submitted their inventory.
2. Harare – A call was held with the lab regarding the recent problems with notifying the NL on the freezer problems A report on the number of samples affected has been received. The site is working with FSTRF to indicate this in

their LDMS. Some samples have had multiple freeze/thaws. Once the LDMS has been updated, it will be useful to identify these samples. The call also addressed inventory issues. Pending an update on their ordering / inventory SOP. Did not submit their LDMS reconciliations, submitted their QC for review, and submitted their inventory.

3. Chennai –Have submitted their LDMS reconciliations, did not submit their QC for review, but submitted their inventory
4. Blantyre – Lab has a new acting manager and a new QA supervisor. The lab supervisor has also left the site at the end of November. Have submitted their LDMS reconciliations, did submit their QC for review, and submitted their inventory
5. Porto Alegre - Did submit their LDMS reconciliations, submitted their QC for review and submitted their inventory.
6. Rio sites – Did not submit their LDMS reconciliations, have submitted their QC for review, and did submit their inventory. Site is currently having issues receiving Roche kits.
7. Lilongwe - Did not submit their LDMS reconciliations, submitted their QC for review, and have submitted their inventory.
8. Chiang Mai – Had no LDMS reconciliations, submitted their QC for review, and submitted their inventory
9. Johannesburg – WITs--Have submitted their LDMS reconciliations, CLS has not submitted their QC for review, and CLS and WITS have not submitted their inventory
10. Soweto – Have submitted their LDMS reconciliations, CLS has not submitted their QC for review, and CLS and Soweto have not submitted their inventory
11. Botswana – Have not submitted their LDMS reconciliations, have not submitted their QC for review, and have not submitted their inventory
12. Kenya – Have submitted their LDMS reconciliations, have not submitted their QC for review, and have submitted their inventory

C. Shipping / QA Status

Pending a shipment from NARI Pune. New QA lists for HIV genotyping and ARV testing have gone out to the sites and shipments are pending from Harare and Kisumu.

IV. HPTN 057

A. General Comments

1. Protocol Version - 2.0 dated 28th October 2009
2. SSP version – 4.0 lab section dated 11th March 2010
3. Enrollment Status – Fully enrolled
4. Date of last SMC call – 21st February 2008.
5. Communiques/Notification of Change to SSP issued since preparation of last SMC report: Clarification memo issued 7-15-2010 clarifying that CK total protein and glucose are not required in HPTN 057 (they had been indicated in section Appendix 1B). PREVIOUSLY REPORTED ON STUDY OPS REPORT
6. Lab-related notes to file/deviations issued since preparation of SMC report:

B. Site Specific

1. Blantyre - No outstanding issues. Site completing the LDMS reconciliations in a timely manner, have not submitted their QC for review, and have submitted their inventory.
2. Santa Casa--Porto Alegre. No outstanding issues. Site completing LDMS reconciliations in a timely manner, have not submitted their QC for review, and have not submitted their inventory.
3. UFMG - No outstanding issues. Site completing LDMS reconciliations in a timely manner, have not submitted their QC for review, and have not submitted their inventory.

4. HSE Rio - No outstanding issues. Site completing LDMS reconciliations in a timely manner. No testing is done on site for this protocol.
5. HNSC--Porto Alegre - Site completing LDMS reconciliations in a timely manner, have not submitted their QC for review, and have not submitted their inventory.

C. Shipping / QA Status

1. A shipping list has been sent to Blantyre. This contains samples for QA testing, PK and resistance testing. Samples have been received by the Network Lab.
2. Specimens from Brazil will be requested mid January 2011

V. HPTN 058

A. General Comments

1. Protocol Version – 2.0 dated 16th September 2008
2. SSP Version – 2.0 dated 5th December 2008
3. Enrollment status – open
4. Date of last SMC call – 10th September 2010
5. Communiqués/Notification of change to SSP issued since preparation of last SMC report: None
6. Lab-related notes to file/deviations issued since preparation of SMC report: None

B. Site Specific

1. Thailand - Site is completing the LDMS reconciliations in a timely, submitted their QC for review, and submitted their inventory.
2. Xinjiang Site - Site is completing the LDMS reconciliations in a timely manner, submitted their QC for review, and have not submitted their inventory.
3. Guangxi - Site is completing the LDMS reconciliations in a timely manner, submitted their QC for review, and have not submitted their inventory.
4. An additional site in Vietnam has been put on hold
5. An additional site in Estonia has been put on hold

C. Shipping / QA Status

No outstanding shipments or requests. QA samples from China have not been requested at this time. Shipment of samples out of China remains problematic. NL will investigate the possibility of performing QA testing at the site labs using USA FDA approved methodologies.

VI. HPTN 061

A. General Comments

1. Protocol Version – Version 2.0, April 2nd 2009
2. SSP Version – Section 11 Version 5.0 December 9th 2010.
3. Enrollment status – Harlem and NYBC have completed enrollment. Atlanta has also completed enrollment.
4. Date of last SMC call – November 8th 2010
5. Communiqués/Notification of change to SSP issued since preparation of last SMC report: Notification of Change to SSP lab section 11 version 5.0 date 9 December 2010.
6. Lab-related notes to file/deviations issued since preparation of SMC report:
 - a. Atlanta – Previously Reported Note to File received for Participant who did not have rapid test done, since there were no controls and the urine and rectal swab that were collected were not picked up by the courier; participant returned for blood draw but refused the collection of urine and rectal swab again. PREVIOUSLY REPORTED
 - b. Fenway – None
 - c. GWU- Waiting on Note to File for mislabeled rectal swab and stored plasma. Previously Reported Note to file received for participant for whom

no plasma was stored due to a hard stick, site will try to bring participant back for redraw. PREVIOUSLY REPORTED

- d. NYBC- None
- e. UCLA- Note to file received for ppt. who refused rectal swab at visit 3.0 (ppt. had also refused at visit 1.0)
- f. Harlem- Previously Reported Note to File received for participant who was a hard stick, so there was no Syphilis test drawn and also no plasma was stored; participant has not returned for redraw. PREVIOUSLY REPORTED
- g. San Francisco- Note to File received for ppt. who had a short blood draw and upon participant return RA did not collect plasma storage or 2nd confirmatory WB.

B. Site Specific

- 1. Fenway - Kelvin Powell named new Study Coordinator as Benny Vega has resigned.
- 2. George Washington University - No new updates
- 3. San Francisco - Study coordinator Chadwick Campbell resigned, no one named as replacement yet.
- 4. Harlem - No new updates
- 5. Atlanta - No new updates
- 6. New York Blood Center - No new updates
- 7. UCLA - No new updates.

C. Shipping / QA Status

QA lists have been sent out for enrollment QA by Scharp.

VII. HPTN 063

A. General Comments

- 1. Protocol Version: Version 1.0 dated 15 September 2008
- 2. SSP version: Version 1.0 dated 26th March 2010 (update in process)
- 3. Enrollment Status: HPTN 063 on hold
- 4. Date of last SMC call: None
- 5. Communiqués/Notifications of Change to SSP issued since preparation of last SMC report: None
- 6. Lab related Notes to file/Deviations issued since preparation of SMC report: None

B. Site Specific

- 1. Thailand
- 2. Brazil
- 3. Zambia

VIII. HPTN 064

A. General Comments

- 1. Protocol Version: 1.0 dated 20February 2010
- 2. SSP version: Version 2.0 dated 12 May 2010
- 3. Enrollment Status: All sites have completed enrollment.
- 4. Date of last SMC call : 01 November 2010
- 5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report: None
- 6. Lab related notes to file/deviations issued since preparation of SMC report:
 - a. Johns Hopkins University - PREVIOUSLY REPORTED November study ops. NL informed plasma wasn't stored for a participant due to a lab accident. Note to File received.
 - b. Emory - PREVIOUSLY REPORTED December study ops NL informed that an enrolled participant used falsified information. Note to File and Protocol Deviation received.

B. Site Specific

1. Bronx - No new updates.
2. Harlem - No new updates.
3. Newark - No new updates.
4. Johns Hopkins University - No new updates.
5. George Washington University - No New updates.
6. University of North Carolina - No new updates.
5. Emory - No new updates

C. Shipping / QA Status

All QA testing has been completed and the data forwarded to SCHARP.

IX. HPTN 066

A. General Comments

1. Protocol Version - 2.0 dated 29th November 2010
2. SSP version – Draft
3. Enrollment Status – Pending – sites not activated.
4. Date of last SMC call – None
5. Communiqués/Notification of Change to SSP issued since preparation of last SMC report: None
6. Lab related notes to file/deviations issued since preparation of SMC report: None
7. Miscellaneous - PBMCs in this study are being used for PK analysis and will follow an SOP developed specifically for this purpose. This study is not storing viable PBMCs and will not follow the Cross-Network PBMC Processing SOP

B. Site Specific

1. UNC - Activities leading to site activation are underway. Training for the site has been completed.
2. JHU - Activities leading to site activation are underway. Training for this site has been completed

X. HPTN 068

A. General Comments

1. Protocol Version – 1.0 dated 06th October 2010
2. SSP version – Draft
3. Enrollment status – pending
4. Date of last SMC call – none
5. Communiqués/Notification of Changes to SSP issued since preparation of last SMC report: None

NL updates

The NL is working on the incidence testing for both HPTN 043 and the domestic trials.

Travel Updates

The NL will be attending the HPTN 068 wet walk-throughs in January and start up in February.

Estelle, LeTanya and Yaw will be attending the HPTN 043 meeting in February.

Implementations Issues and Problems Summary January 2011

052

The study team is in the process of informing all participants about the updated advice from the WHO that recommends that HIV-infected persons should start taking ART at CD4 cell counts of 350 and below. This information is being conveyed via an information sheet that also informs participants of whether the local health and government authorities are adopting these new WHO guidelines. The study team is tracking the process until all participants have been informed.

Refer to the Network Laboratory report for any issues and problems related to the clinical site laboratories.

058

The study team was concerned over apparent decreases in maintenance dosing over time and held conference calls with individual sites in December to clear the issue.

061

Retention is right now the greatest concern in study implementation. Fortunately, the follow-up visit windows in 061 are large creating opportunity for bringing participants who have missed their target window in for their 6 or 12 month visits. Unfortunately, the windows are starting to close for the 6 month visit, meaning that retention for that timepoint will soon be fixed.

063

The Brazilian central IRB (CONEP) took longer than expected to approve the study. The original submission was on 04 May 2009. The approval is dated for 16 December 2009, although the site was not notified of the approval until 03 February 2010. The site received an official announcement that on 24 September 2010 they received approval of Foreign Clearance (Number 14846 for HPTN 063).

After the HPTN annual meeting, the HPTN 063 protocol team decided that enrollment would be put on hold until the ACASI issues that arose after the Thai site was initiated were resolved. The protocol team closely monitored the piloting of the new ACASI to ensure a more representative sample of participants were piloted to receive accurate feedback before it was finalized. All three sites have piloted the new ACASI instrument and have provided feedback to the team.

The Protocol Team has reviewed the feedback from the sites and have revised the ACASI accordingly. The updated version of the ACASI is being translated and the audio is being finalized. Sites are currently submitting the newest version of the ACASI to their local IRB.

Sites have procured touchscreen laptops, similar to what is being used in other network studies that are using an ACASI system for data collection. The touchscreen laptops were not initially budgeted for in this study budget so the team is revisiting the original budget and looking for ways to accommodate the additional cost.

A Letter of Amendment (LoA #2) was sent for DAIDS approval on December 8, 2010 and approval was received in December 10, 2010. The contents of the amendment include the following:

- Updates to the Protocol Team Roster
- Clarification on the point of enrollment for study participants

- Note: The point of enrollment was changed to allow for sites to use one set of PTIDs for screening and enrollment and allow for data collection to be the official point of enrollment
- Correction regarding the shipment of specimens
- Removal of old references
- Clarification on vaginal and rectal swabs collection
- Clarification on testing for gonorrhea and Chlamydia

LoA #2 was originally intended as a Clarification Memo (CM) but upon review of the CM, DAIDS Regulatory requested that it be submitted as a LoA due to bullet #2 listed above.

Sites were notified of the approval on December 10, 2010 and instructed to notify their local IRB and/or ethical committees for review and approval.

064

Retention is being monitored very closely at all sites to ensure study targets are met. Weekly reports are collected from each site to monitor retention.

065

On September 28, 2010, FHI was informed that MedStar Health Research Institute (MHRI), the body that governs research at Washington Hospital Center, has declined to participate in the study. Wafaa El-Sadr and Bernie Branson (study chair and co-chair) are following up with the president of MHRI as well as the IoR, Dr. Margo Smith, to determine if there is still a possibility for Washington Hospital Center to participate in the study as both a test and care site. The NIH has offered to contact Washington Hospital Center as well. The study team has decided to move forward without Washington Hospital Center at this time, as most sites have now completed their IRB and contract approvals and momentum is high to begin the study. Dr. El-Sadr, NIH, and the DC DOH will continue to communicate with Washington Hospital Center. If, at a later date, Washington Hospital Center decides to participate, SCHARP has confirmed that they may be randomized separately.

066

The CTA took significantly longer to finalize than was originally anticipated. As noted above, the final CTA was executed in mid-December. It was originally expected late 3rd quarter or early 4th quarter of 2010.

LoA#1 to Version 2.0 of the protocol was required by DAIDS in order to modify the informed consent forms to include mention of the iPrEx study results, which were released in late November 2010. The sites have submitted their amended informed consent forms to their IRBs for approval along with Version 2.0 of the protocol and are waiting for approval before we are able to schedule retraining and move forward. Study start-up is anticipated for late January or early February 2011.

067

The Clinical Trial Agreement has not yet been finalized with Gilead. RAB determined that data collected in the CASI does not need to be compliant with Title 21 CFR Part 11.

068

The site is not an approved HPTN site yet, nor has the South African IRB approved the study. In addition, there are staffing and feasibility concerns that will delay activation and slow the enrollment.

Report for HPTN Study Operations Group

HPTN 046

A phase III trial to determine the efficacy and safety of an extended regimen of nevirapine in infants born to HIV-infected women to prevent vertical transmission during breastfeeding

Based on available data through: 7 January 2011

Participating Study Sites:

CAPRISA Umlazi; Durban, South Africa
Muhimbili Hospital; Dar es Salaam, Tanzania
Mulago Hospital; Kampala, Uganda
Chitungwiza Clinics; Chitungwiza, Zimbabwe

Study Implementation Status:

All infants have now completed the 6 months study product dosing period. Follow-up will continue until the last infant completes the 18 month visit which is expected to occur around July 2011.

Analysis of the 6 month endpoint data is complete. An abstract discussing the details of the results has been submitted as a late-breaker to CROI for the meeting at the end of February/early March.

Accrual Status:

The study enrolled 1678 mother-infant pairs [1700 infants in all].

Status of Intervention Delivery:

Blinded study product has been discontinued in all infants.

Retention Status:

There have been no retention issues identified at this time.

Implementation Issues and Problems:

No issues at this time.

Report for HPTN Study Operations Group

HPTN 052

A Randomized Trial to Evaluate the Effectiveness of Antiretroviral Therapy plus HIV Primary Care versus HIV Primary Care Alone to Prevent the Sexual Transmission of HIV-1 In Serodiscordant Couples

Based on available data through: 4 January 2011

Participating Study Sites:

Gaborone, Botswana
Porto Alegre and Rio de Janeiro, Brazil
Chennai, India
Pune, India
Blantyre, Malawi
Lilongwe, Malawi
Johannesburg, South Africa
Soweto, South Africa
Chiang Mai, Thailand
Harare, Zimbabwe
Kisumu, Kenya

Study Implementation Status:

All sites listed above are operating under Version 3.0 of the protocol. Enrollment is closed as of April 2010. The total final enrollment was confirmed by SCHARP at 1763 couples.

A full amendment is being drafted to include incorporation of all Letters of Amendment and Clarification Memos, and new information related to the EAE reporting system. In addition, the team is discussing which WHO Stage 3 clinical conditions should be incorporated into the protocol for initiation of ART (right now the protocol only lists WHO Stage 4 clinical conditions).

Retention Status:

Overall, 90% of all couples are retained in the study. 97% of all Index cases are retained in the study, with 6% of these Indexes retained without their partners. Refer to the SCHARP "Couples Status" retention summary available on Atlas for site-specific information.

Implementation Issues and Problems:

The study team is in the process of informing all participants about the updated advice from the WHO that recommends that HIV-infected persons should start taking ART at CD4 cell counts of 350 and below. This information is being conveyed via an information sheet that also informs participants of whether the local health and government authorities are adopting these new WHO guidelines. The study team is tracking the process until all participants have been informed.

Refer to the Network Laboratory report for any issues and problems related to the clinical site laboratories.

Report for HPTN Study Operations Group

HPTN 057

A Phase I Open Label Trial of the Safety and Pharmacokinetics of Tenofovir Disoproxil Fumarate in HIV-1 Infected Pregnant Women and their Infants

Based on available data through: 10 January 2011

Participating Study Sites:

Malawi - Queen Elizabeth Central Hospital, Malawi College of Medicine-JHU Research Project, Blantyre (QECH)

Brazil - Federal University of Minas Gerais, Belo Horizonte (UFMG)

- Irmandade Santa Casa de Misericordia de Porto Alegre, Porto Alegre (Santa Casa)
- Hospital dos Servidores do Estado – Serviço de Doenças Infecciosas, Rio de Janeiro (HSD)
- Hospital Nossa Senhora da Conceicao Serviço de Infectologia, Porto Alegre (Conceicao)

Study Implementation Status: Enrollment is and Follow-up of Cohorts 1, 2 and 3 was completed in Sept 2009. The protocol was amended to add a fourth cohort looking at a maternal dose during labor and daily infant dosing for 1 week. **Enrollment into Cohort 4 was completed in late November 2010.** Follow-up is for 1 year. The expected study completion date is November - December 2011.

Accrual Status:

Below is the site reported enrollment summary for Cohorts 1, 2, 3 and 4; refer also to the SHARP enrollment summary.

Site	# Evaluable Mother/Infant Pairs Enrolled			
	Cohort 1	Cohort 2	Cohort 3	Cohort 4
Queen Elizabeth Central Hospital, Blantyre Malawi	24	16	15	15
Santa Casa, Porto Alegre Brazil (pending drug import approval)	3	4	4	2
University of Minas Gerais, Belo Horizonte Brazil	3	1	2	3
Conceicao, Porto Alegre Brazil	-	-	4	5
Hospital do Servidores, Rio de Janeiro Brazil	-	-	5	6
Total	30	21	30	31

Status of Intervention Delivery:

There have been no reported significant problems with the dispensing of tenofovir to the mothers or infants.

Retention Status:

Two mother/infant pairs for Cohorts 1 – 3 have been lost to follow-up.

Implementation Issues and Problems: none.

Report for HPTN Study Operations Group

HPTN 058

A Phase III randomized controlled trial to evaluate the efficacy of drug treatment in prevention of HIV infection and death among opiate dependent injectors

Based on data available through 07 January 2011

Participating Study Sites:

- Xinjiang Uighur Autonomous Region, Centers for Disease Control and Prevention, Xinjiang, China
- Guangxi Zhuang Autonomous Region, Centers for Disease Control and Prevention, Heng County, Guangxi, China
- Guangxi Zhuang Autonomous Region, Centers for Disease Control and Prevention, Nanning, Guangxi, China
- Research Institute for Health Sciences, Chiang Mai, Thailand

Study Implementation Status:

Enrollment in Chiang Mai was capped at 202 participants in October 2009. Xinjiang has enrolled 336 participants. Heng County has enrolled 309 participants. Nanning has enrolled 75 participants.

The Chinese team members continue to work on recruiting among a higher risk cohort and improving retention and adherence (both counseling and medication).

Discussions are under way to formulate a plan to allow Suboxone compassionate use for participants who have completed 058 follow-up in both China and Thailand.

A safety phase completion review call took place on December 6th with the Nanning site.

Accrual Status:

	Chiang Mai	Nanning	Heng County	Xinjiang
Date First Screened	11-Apr-07	6-May-10	19-Dec-08	19-Dec-08
Date First Enrolled	30-May-07	19-May-10	24-Dec-08	21-Dec-08
# Individuals Screened	281	179	652	619
# Individuals Enrolled	202	75	309	336

Status of Intervention Delivery:

Study drug has been generally well tolerated.

Retention Status:

All Sites	
Week 26	89%
Week 52	83%
Week 78	83%
Week 104	89%
Week 130	80%
Week 156	89%

Implementation Issues and Problems:

The study team was concerned over apparent decreases in maintenance dosing over time and held conference calls with individual sites in December to clear the issue.

Report for HPTN Study Operations Group

HPTN 061

Feasibility study of a community-level, multi-component intervention for Black men who have sex with men in preparation for a community-level randomized trial to test the efficacy of the intervention in reducing HIV incidence among Black men who have sex with men

Based on data available through: 05 January 2010

Participating Study Sites:

- Ponce de Leon Center CRS (site 5802) and Hope Clinic CRS (site 31440) in Atlanta and Decatur, Georgia, respectively
- San Francisco Vaccine and Prevention CRS in San Francisco, California (site 30305)
- New York Blood Center (NYBC)/Union Square CRS (site 31605) and Harlem Prevention Center CRS (site 30276) in New York City, New York
- University of California at Los Angeles (UCLA) Vine Street CRS (site 31607) in Los Angeles, California
- The Fenway Institute CRS (site 31602) in Boston, Massachusetts
- George Washington University CRS (site 31608) in Washington, D.C.

Study Implementation Status:

All sites for the HPTN 061 protocol have finished enrolling and following participants. The last date of index partner (participant-referred) enrollment was 30 days after the last date of community recruitment.

Site	Date of Activation	Date of First Enrollment	Date of Completion of Community Recruitment
The Fenway Institute	06 July 2009	17 July 2009	29 Sept 2010
George Washington University	20 July 2009	28 July 2009	28 Sept 2010
San Francisco Vaccine and Prevention CRS	11 August 2009	13 August 2009	29 Sept 2010
New York Blood Center	24 August 2009	01 October 2009	27 July 2010
Hope Clinic CRS	04 September 2009	16 September 2009	16 Sept 2010
UCLA	25 September 2009	29 September 2009	29 Sept 2010
Ponce de Leon CRS	09 October 2009	26 February 2010	16 Sept 2010
Harlem Prevention Center	05 January 2010	08 January 2010	17 June 2010

Final Site-Reported Total Enrollment:

Fenway	GWU	Emory: Ponce + Hope	San Fran	UCLA	NYBC	Harlem	TOTAL
237	227	295	203	284	158	154	1,558

Status of Intervention Delivery:

Sites continue to provide HIV and STI testing and referral as well as Peer Health Navigation to enrolled participants. All sites have now completed enrollment (last date for enrollment was 29 October 2010). Individual interviews have been completed at most sites.

Recruitment Status:

All recruitment has been completed. Total enrollment was 1558.

Retention Status:

All sites are conducting six month visits and (except Harlem) have conducted, 12 month (final) visits. Retention is not strong, but is improving slowly, up to a study-wide average of 76% for the 6 month visit. There is less disparity now between sites in their 6 month retention rate than previously, from a low of 64% (Emory) to a high of 90% (Harlem). Calls have been conducted between site staff and the protocol co-chairs on the topic of retention for each site and retention remains the primary focus of the monthly study team calls.

Retention at the 12 month (exit) visit is low at 69% and ranging from a site low of 57% to a site high of 84% at NY Blood Center.

Implementation Issues and Problems:

Retention is right now the greatest concern in study implementation. Fortunately, the follow-up visit windows in 061 are large creating opportunity for bringing participants who have missed their target window in for their 6 or 12 month visits. Unfortunately, the windows are starting to close for the 6 month visit, meaning that retention for that timepoint will soon be fixed.

Report for HPTN Study Operations Group

HPTN 062

Feasibility and Acceptability Study of an Individual-Level Behavioral Intervention for Individuals with Acute and Early HIV-Infection

Based on data available through: 06 January 2011

Participating Study Sites:

- University of North Carolina Project, Kamuzu Central Hospital, Lilongwe, Malawi

Study Implementation Status:

Lilongwe site was activated on 24 February 2010 and began enrolling in April 2010. Enrollment is dependent on identifying acutely infected people in the CHAVI 001 study, hence enrollment is sporadic. A broader screening strategy in the CHAVI 001 study has been in place for the past three months, yielding a higher recruitment number for 062.

Version 3 of the protocol has been in effect at the site since IRB approval was received 30 September.

Accrual Status (completed at all sites):

Sixteen participants have been enrolled to date.

Status of Intervention Delivery:

Most study visits have been completed on time; retention is high. No social harms have been reported.

Retention Status:

See the SCHARP report

Implementation Issues and Problems:

None

Report for HPTN Study Operations Group

HPTN 063 Preparing for International Prevention Trials Involving HIV-Infected Individuals in Care Settings

Based on data available through: 05 January 2011

Participating Study Sites:

- Matero Clinic CRS; Lusaka, Zambia
- Chiang Mai University AIDS Prevention CRS; Chiang Mai, Thailand
- Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS; Rio de Janeiro, Brazil

Study Implementation Status:

Version 1.0 of the protocol was approved on 16 September 2008 and distributed to sites upon notification of approval (17 September 2008).

The Thai site was activated on 26 March 2010 and enrolled their first participant on 01 April 2010.

The Brazil site has received local and central IRB (CONEP) approvals. The site received verbal Ministry of Health (MOH) approval on 22 July 2010. The MOH has sent this information to the American Embassy for State Department clearance. The site received an official announcement that on 24 September 2010 they received approval of Foreign Clearance (Number 14846 for HPTN 063).

Enrollment was paused on 22 June 2010 due to ACASI issues discussed during the 2010 HPTN Annual Meeting (see details below in the **Implementation Issues and Problems** section). However, the Thailand site is still actively recruiting and enrolling participants for the qualitative component.

Sites are currently reviewing the drafts of version 2.0 of the SSP. The HPTN CORE is in the process of receiving feedback to make revisions before the final version is released.

Site activation activities are complete at all sites. The site training schedule was as follows: Thailand (25-29 January, 2010 - **Completed**), Zambia (21-27 October 2010 - **Completed**), and Brazil (1-5 March, 2010 - **Completed**). Retraining for the Brazil site is currently being discussed.

Accrual Status:

Below is site-reported screening and enrollment data ending 05 January 2011 refer also to the SCHARP enrollment summary.

Retention Status:

Refer to the SCHARP retention summary.

HPTN-063 Cumulative Screening and Enrollment Report							
Based on Site-Reported Information							
January 5, 2011							
Site (Quantitative Participants)	Date of First Screening	Date of First Enrollment	No. Pre-Screened	No. Report No Unprotected Sex	No. Not Receiving Care	Total No. Screened	Total No. Enrolled
Brazil: Rio de Janeiro (IPEC CRS)							
Women							
Heterosexual Men							
MSM							
Thailand: Chiang Mai							
Women			313	0	0	288	33
Heterosexual Men			229	0	0	213	16
MSM			55	0	0	43	12
Zambia: Lusaka (Metero Clinic CRS)							
Women							
Heterosexual Men							
TOTAL	NA	NA	597	0	0	544	61

Thailand (Qualitative Interviews)	Women	Heterosexual Men	Stakeholders	MSM	Thailand (Focus Groups)	Date of Focus Group	No. of participants
Date of Interview	17-May-10	22-Jul-10		17-May-10	Session 1	17-Jun-10	8
	22-Jul-10			19-May-10	Session 2		
					Session 3		
					Session 4		
					TOTAL	1	8
TOTAL	2	1	0	2			

Implementation Issues and Problems:

The Brazilian central IRB (CONEP) took longer than expected to approve the study. The original submission was on 04 May 2009. The approval is dated for 16 December 2009, although the site was not notified of the approval until 03 February 2010. The site received an official announcement that on 24 September 2010 they received approval of Foreign Clearance (Number 14846 for HPTN 063).

After the HPTN annual meeting, the HPTN 063 protocol team decided that enrollment would be put on hold until the ACASI issues that arose after the Thai site was initiated were resolved. The protocol team closely monitored the piloting of the new ACASI to ensure a more representative sample of participants were piloted to receive accurate feedback before it was finalized. All three sites have piloted the new ACASI instrument and have provided feedback to the team.

The Protocol Team has reviewed the feedback from the sites and have revised the ACASI accordingly. The updated version of the ACASI is being translated and the audio is being finalized. Sites are currently submitting the newest version of the ACASI to their local IRB.

Sites have procured touchscreen laptops, similar to what is being used in other network studies that are using an ACASI system for data collection. The touchscreen laptops were not initially budgeted for in this study budget so the team is revisiting the original budget and looking for ways to accommodate the additional cost.

A Letter of Amendment (LoA #2) was sent for DAIDS approval on December 8, 2010 and approval was received in December 10, 2010. The contents of the amendment include the following:

- Updates to the Protocol Team Roster
- Clarification on the point of enrollment for study participants
 - Note: The point of enrollment was changed to allow for sites to use one set of PTIDs for screening and enrollment and allow for data collection to be the official point of enrollment
- Correction regarding the shipment of specimens
- Removal of old references
- Clarification on vaginal and rectal swabs collection
- Clarification on testing for gonorrhea and Chlamydia

LoA #2 was originally intended as a Clarification Memo (CM) but upon review of the CM, DAIDS Regulatory requested that it be submitted as a LoA due to bullet #2 listed above.

Sites were notified of the approval on December 10, 2010 and instructed to notify their local IRB and/or ethical committees for review and approval.

Report for HPTN Study Operations Group
HPTN 064
Women's HIV Seroprevalence Study (ISIS)
Based on data available through: 05 January 2011

Participating Study Sites:

- Emory University, Atlanta, Georgia (Ponce de Leon Center CRS and Hope Clinic CRS)
- Johns Hopkins Adult AIDS CRS, Baltimore, Maryland
- University of North Carolina-Chapel Hill, North Carolina (UNC AIDS CRS and Wake County Health and Human Services CRS)
- Columbia University, New York, New York (Bronx-Lebanon Hospital Center CRS and Harlem Prevention Center CRS)
- New Jersey Medical School Adult Clinical Trials Center, Newark, New Jersey
- George Washington University School of Public Health and Health Services, Washington D.C.

Study Implementation Status:

HPTN 064 successfully completed enrollment on 26 July 2010 enrolling 2099 women.

The qualitative sites have successfully completed all qualitative interviews and focus groups. The FHI CORE has completed coding the qualitative interviews, female focus groups and male focus groups. Preliminary code reports have been prepared for the upcoming face-to-face analysis meeting to be held January 24-28, 2011 at FHI's RTP office.

All study visits will be completed by February 28, 2011.

Accrual Status:

Please see SCHARP Enrollment Report.

Status of Intervention Delivery:

N/A

Retention Status:

Please see SCHARP Retention Report.

Implementation Issues and Problems:

Retention is being monitored very closely at all sites to ensure study targets are met. Weekly reports are collected from each site to monitor retention.

Report for HPTN Study Operations Group

HPTN 065

TLC-Plus: A Study to Evaluate the Feasibility of an Enhanced Test, Link to Care, Plus Treat Approach for HIV Prevention in the United States

Based on available data through: 7 January 2011

Participating Study Sites:

HPTN 065 includes two intervention communities (Washington, D.C. and the Bronx, New York) and four comparator communities (Miami, Florida; Philadelphia, Pennsylvania; Chicago, Illinois; and Houston, Texas). The team has identified a total of 77 sites (38 test sites and 39 care sites) located in Washington, D.C. and the Bronx, New York that will actively participate in the study.

Bronx:

The protocol team has finalized a list of 19 test sites (including 9 hospitals) and 20 care sites to participate in the study. The team is moving forward with site contracts and IRB submissions for these sites.

Washington, DC.

The protocol team has finalized a list of 19 test sites (including 7 hospitals) and 19 care sites to participate in the study. The team is moving forward with site contracts and IRB submissions for these sites. Initially the team had planned to include 20 test and 20 care sites (including 8 hospitals), but after much consideration, the team has decided to move forward without Washington Hospital Center, as they have repeatedly expressed their desire not to participate in the study and the remaining study sites are ready to begin. Some measures are still being taken on the part of the NIH and the Department of Health to encourage them to participate. If they decide to do so at a later date, they will be included and randomized separately.

Study Implementation Status:

Overall Plan for Implementation:

1. Finalize site selection and notify sites
2. Set up minimal subcontracts with all sites (using non-FI budgets)
3. Obtain all IRB approvals
4. Begin Provider Survey component with Care Sites
5. Randomize sites
6. Conduct operational trainings
7. Begin Expanded HIV Testing, Linkage-to-Care, and Viral Suppression study components
8. Select Prevention for Positive Sites
9. Begin Prevention for Positives and Patient Survey components

Randomization:

The first sub-set randomization was done in late October, 2010 with 10 HIV care sites in Washington, DC who had both IRB approval and a signed contract. The operational training for the 5 DC care sites randomized to the financial incentive arm for viral suppression is scheduled for Tuesday, January 11, 2010, in Washington, DC. Randomization of the remaining Washington, D.C. sites is anticipated for late January when all site contracts are finalized and all IRB approval has been obtained. All Bronx sites have now obtained IRB approval and a signed contract; SCHARP is currently working on the randomization of these sites and is expected to complete it by mid-January.

Study Start Date:

The study officially started on September 29, 2010, with the launch of the Provider Survey. The study has been registered in ClinicalTrials.gov with a start date of September 2010. The viral suppression study component will start on February 1, 2011 for the 10 HIV care sites randomized in Washington, D.C. Expanded HIV testing in hospital in-patient and emergency departments will begin February 1, 2011.

Protocol Status:

The protocol received final approval for V1.0 from DAIDS on March 16, 2010. Subsequently, Version 2.0 of the protocol received final approval from DAIDS on July 20, 2010.

IRB Update:

The protocol (V1.0) was submitted to a central IRB (Copernicus) for review, and was granted unconditional approval on May 21, 2010. Version 2.0 of the protocol was approved by Copernicus on July 27, 2010. The final Provider Survey and all associated participant materials were approved as an amendment by Copernicus on September 23, 2010.

All sites have the option of using their own local IRB or the central IRB. Given this choice, approximately 50% of the sites are using the central IRB and 50% of the sites are using their own local IRBs. The table below outlines the number IRB submissions and approval by site and IRB type for each intervention community.

To date, overall IRB approval status is as follows:

- **DC:** 95% of the HIV test sites and 89% of the HIV care sites have obtained IRB approval
- **Bronx:** 100% of the HIV test sites and 100% of the HIV care sites have obtained IRB approval

	Total	Central IRB			Local IRB		
		Using	Submitted	Approved	Using	Submitted	Approved
Washington, D.C.							
Test Sites	19	12	12	12	7	7	6
Care Sites	19	13	13	13	7	7	5
Bronx, NY							
Test Sites	19	8	8	8	11	11	11
Care Sites	20	8	8	8	12	12	12

Contract Update:

The team has generated and sent contracts to all participating institutions in Washington, D.C. and the Bronx, except for one institution in Washington, D.C. (see Implementation Issues below)

- **DC:** 95 % of the HIV test sites and 95% of the HIV care sites have finalized a contract with FHI
- **Bronx:** 100% of HIV test sites and 100% of the HIV care sites have finalized a contract with FHI

Expansion of HIV testing:

- Social Mobilization: The first social mobilization ads began on November 19, 2010 in DC on social networking and dating websites and in print. The ads will continue in various venues throughout DC through May 31, 2010. The NY DOH has approved the Bronx ad and the study team is currently working with the ad agency on a distribution plan.
- Expanded Testing in Hospitals: Seven hospitals in DC and nine in the Bronx have been selected to participate in this component of the study. The study team is preparing expanded testing implementation plan templates to be completed by the hospitals. Face-to-face meetings and/or conference calls for all participating hospitals are being planned for January and February, 2011 in order to discuss how each institution will expand testing in their in patient and ED settings and facilitate implementation of this.

Linkage-to-Care (L2C) and Viral Suppression (VS):

- Contracts and IRB approvals have been obtained for all Bronx test and care sites; the team is still working to obtain contract and IRB approvals for 1 test and 2 care sites in D.C.
- An operational training for sites randomized to the financial incentive arm for viral suppression is planned for January 11, 2011.
- Training for sites randomized to the standard of care arm for viral suppression will occur at a later date, once the timeline for beginning the Linkage-to-Care component has been developed and the remaining test and care sites randomized.

Prevention for Positives (PfP):

- The study team is working to update the CARE+ program.
- Once all sites have been randomized for the Viral Suppression study component, a subset of sites will be chosen to participate in PfP.

Patient and Provider Surveys:

- Both the patient and provider surveys have been finalized and the patient survey has been translated into Spanish.
- The provider survey was launched on September 29, 2010, with care sites that have both a contract and IRB approval for the survey in place. To date, the survey has been sent to ART-prescribing providers at 13 out of 20 care sites in Washington, D.C., and 11 out of 20 care sites in the Bronx.
- The current response rate is 51%.

Site and DOH Surveys:

- Test site, care site, and DOH surveys developed by the sub-group have been approved by the study chair and co-chair. Surveys will be piloted by test and care sites in February, 2011 once SCHARP has completed programming of the surveys in the Atlas web portal.

Training Update:

- An Investigator Meeting for DC providers was held on October 28, 2010 in Washington, D.C., and for Bronx providers on December 6, 2010, in Bronx, NY.
- A study operational training is being planned for January 11, 2011 for the 5 Washington, D.C. sites randomized to use financial incentives to promote viral suppression.

Reviews:

- The study team presented the overall study design to the Prevention Trials Data Safety and Monitoring Board (DSMB) on December 9, 2010. The DSMB provided

written comments and questions to the team; the protocol chair and co-chair is working with the team on a response to the queries.

Accrual Status: N/A

Retention Status: N/A

Implementation Issues and Problems:

On September 28, 2010, FHI was informed that MedStar Health Research Institute (MHRI), the body that governs research at Washington Hospital Center, has declined to participate in the study. Wafaa El-Sadr and Bernie Branson (study chair and co-chair) are following up with the president of MHRI as well as the IoR, Dr. Margo Smith, to determine if there is still a possibility for Washington Hospital Center to participate in the study as both a test and care site. The NIH has offered to contact Washington Hospital Center as well. The study team has decided to move forward without Washington Hospital Center at this time, as most sites have now completed their IRB and contract approvals and momentum is high to begin the study. Dr. El-Sadr, NIH, and the DC DOH will continue to communicate with Washington Hospital Center. If, at a later date, Washington Hospital Center decides to participate, SCHARP has confirmed that they may be randomized separately.

Report for HPTN Study Operations Group

HPTN 066 Dose-Proportionality And Intra-Individual Variability Of Intracellular Tenofovir Diphosphate And Emtricitabine Triphosphate In Healthy Volunteers

Based on data available through: 6 January 11

Participating Study Sites:

- Johns Hopkins University, Baltimore MD; USA
- University of North Carolina at Chapel Hill, Chapel Hill NC; USA

Study Implementation Status:

Version 2.0 of the protocol was granted final approval on 29 November 2010 and was distributed to the sites 1 December 2010. Letter of Amendment (LoA) #1 to HPTN 066, Version 2.0 was approved by DAIDS on 16 December 2010. Sites are currently submitting the new version of the protocol, LoA, and updated informed consent forms to their local IRB for approval.

The Clinical Trial Agreement (CTA) was signed on 13 December 2010. Study product is estimated to be available next week.

Study product will be available for shipment to sites when sites have completed protocol registration of Version 2.0 of the protocol. Katie Shin (Pharmaceutical Affairs Branch of DAIDS) will send out ordering instructions the first week of January. A brief re-training will be scheduled with sites since it has been more than 8 weeks since the initial training.

Accrual Status:

Pending, no sites have been activated.

Retention Status:

Pending, no sites have been activated.

Implementation Issues and Problems:

The CTA took significantly longer to finalize than was originally anticipated. As noted above, the final CTA was executed in mid-December. It was originally expected late 3rd quarter or early 4th quarter of 2010.

LoA#1 to Version 2.0 of the protocol was required by DAIDS in order to modify the informed consent forms to include mention of the iPrEx study results, which were released in late November 2010. The sites have submitted their amended informed consent forms to their IRBs for approval along with Version 2.0 of the protocol and are waiting for approval before we are able to schedule retraining and move forward. Study start-up is anticipated for late January or early February 2011.

Report for HPTN Study Operations Group

HPTN 067

The ADAPT study:

A Phase II, Randomized, Open-Label, Pharmacokinetic and Behavioral Study of the Use of Intermittent Oral Emtricitabine/Tenofovir Disoproxil Fumarate Pre-Exposure Prophylaxis (PrEP)

Based on data available through January 7, 2010

Participating Study Sites:

- The Thailand Ministry of Public Health–United States (U.S.) Centers for Disease Control (CDC) collaboration (TUC) Silom Community Clinic in Bangkok, Thailand (31681)
- The Emavundleni Centre, The Desmond Tutu HIV Foundation in Cape Town, South Africa (30346)

Study Implementation Status:

Version 1.0 dated September 20, 2010 of the protocol was granted final approval 23 September 2010 and distributed to the sites on the same day. The CASI and Weekly Interview Guide have been drafted and are in the process of being finalized. Other implementation materials (including counseling materials and the SSP) are currently being drafted. The team is preparing a Letter of Amendment to incorporate the recent iPrEx results into the template Informed Consent Forms as well as other minor corrections and modifications.

The Cape Town site submitted the protocol and Informed Consent Forms (ICFs) for both initial local IRB review and Medicines Control Council (MCC) review in November. The results of both reviews should be available in January.

The Bangkok site is also currently working towards fulfilling activation requirements including preparation of local ICFs and translations for IRB/MOPH review. The Bangkok site has begun the CDC Scientific Review process through submitting for in-country clearance. The site hopes to submit the translated protocol for MOPH IRB review in January. The site is hoping to obtain approvals from both the MOPH IRB and the CDC by April.

Accrual Status:

Pending, no sites have been activated.

Status of Intervention Delivery:

Pending, no sites have been activated.

Retention Status:

Pending, no sites have been activated.

Implementation Issues and Problems:

The Clinical Trial Agreement has not yet been finalized with Gilead. RAB determined that data collected in the CASI does not need to be compliant with Title 21 CFR Part 11.

Report for HPTN Study Operations Group

HPTN 068

Effects of cash transfer for the prevention of HIV in young South African women

Based on data available through: 06 January 2011

Participating Study Sites:

- MRC/Wits Rural Public Health and Health Transitions Research Unit (Agincourt)

Study Implementation Status:

The version 1.0 protocol was approved on 06 October 2010 and was distributed the same day. Protocols, consents, and other essential documents have been submitted to University of North Carolina and the University of Witwatersrand IRBs. UNC has given approval for the study; University of Witwatersrand Ethics Committee has disapproved the protocol due to the Friendship Grid questionnaire. The team is revising the grid to remove identifiers from this questionnaire and will resubmit to the IRB in January.

Protocol-specific training was conducted in December. Several concerns were raised during the training related to feasibility of the rapid enrollment, the training of the nurses and counselors, OCSO site approval and final IRB approval. More intensive training for lab, nurses, counselors and other field work staff will be conducted in January. Activation will be delayed at least until late February. Once the site is activated, it will do a graduated enrollment to allow staffs time to become familiar with all the procedures.

Most of the necessary lab equipment is now available and operational at the new laboratory; a Project Manager and a Lab Manager are now hired and are at the site.

Accrual Status (completed at all sites):

Not applicable.

Status of Intervention Delivery:

Not applicable; study has not been activated.

Retention Status:

Not applicable.

Implementation Issues and Problems:

The site is not an approved HPTN site yet, nor has the South African IRB approved the study. In addition, there are staffing and feasibility concerns that will delay activation and slow the enrollment.

Appendix: HPTN Protocols and INDs

Protocol #		IND	IND Sponsor	Study Status
HPTN 046	Phase III Trial to Determine the Efficacy and Safety of an Extended Regimen of Nevirapine in Infants Born to HIV Infected Women to Prevent Vertical HIV Transmission During Breastfeeding	72,592	DAIDS	Closed to Accrual
HPTN 052	A Randomized Trial to Evaluate the Effectiveness of Antiretroviral Therapy Plus HIV Primary Care versus HIV Primary Care Alone to Prevent the Sexual Transmission of HIV-1 in Serodiscordant Couples	68,535	DAIDS	Closed to Accrual
HPTN 057	A Phase I Open Label Trial of the Safety and Pharmacokinetics of Tenofovir Disoproxil Fumarate in HIV-1 Infected Pregnant Women and their Infants	72,531	DAIDS	Closed to Accrual
HPTN 058	A Phase III randomized controlled trial to evaluate the efficacy of drug treatment in prevention of HIV infection and death among opiate dependent injectors	73,797	DAIDS	Enrolling
HPTN 067	A Phase II, Randomized, Open-Label, Pharmacokinetic and Behavioral Study of the Use of Intermittent Oral Emtricitabine/Tenofovir Disoproxil Fumarate Pre-Exposure Prophylaxis (PrEP)	71,589	DAIDS	In Development