HPTN 094 − INTEGRA: A Vanguard Study of Health Service Delivery in a Mobile Health Delivery Unit to Link Persons who Inject Drugs to Integrated Care and Prevention for Addiction, HIV, HCV and Primary Care
LIVE Open Report − September 15, 2025
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Table O12 − Protocol Deviations and Enrollment Violations by Site

	Overall	New York − Bronx Prevention	Los Angeles − Vine Street	Washington DC − Washington Circle	Houston AIDS Research Team CRS	Philadelphia
Number of Protocol Deviations and Enrollment Violations [1]	272	19	124	13	40	76
Type of Protocol Deviation						
Inappropriate enrollment	8/272 (2.9%)	0/19 (0.0%)	8/124 (6.5%)	0/13 (0.0%)	0/40 (0.0%)	0/76 (0.0%)
Failure to follow randomization or blinding procedures	1/272 (0.4%)	0/19 (0.0%)	0/124 (0.0%)	0/13 (0.0%)	0/40 (0.0%)	1/76 (1.3%)
Conduct of non−protocol procedure	24/272 (8.8%)	0/19 (0.0%)	20/124 (16.1%)	2/13 (15.4%)	2/40 (5.0%)	0/76 (0.0%)
Improper SAE	0/272 (0.0%)	0/19 (0.0%)	0/124 (0.0%)	0/13 (0.0%)	0/40 (0.0%)	0/76 (0.0%)
Unreported SAE	4/272 (1.5%)	0/19 (0.0%)	2/124 (1.6%)	0/13 (0.0%)	0/40 (0.0%)	2/76 (2.6%)
Breach of confidentiality	2/272 (0.7%)	0/19 (0.0%)	0/124 (0.0%)	0/13 (0.0%)	0/40 (0.0%)	2/76 (2.6%)
Physical assessment deviation	0/272 (0.0%)	0/19 (0.0%)	0/124 (0.0%)	0/13 (0.0%)	0/40 (0.0%)	0/76 (0.0%)
Lab assessment deviation	188/272 (69.1%)	18/19 (94.7%)	65/124 (52.4%)	10/13 (76.9%)	36/40 (90.0%)	59/76 (77.6%)
Staff performing duties that they are not qualified to perform	0/272 (0.0%)	0/19 (0.0%)	0/124 (0.0%)	0/13 (0.0%)	0/40 (0.0%)	0/76 (0.0%)
Use of non−IRB/EC−approved materials	0/272 (0.0%)	0/19 (0.0%)	0/124 (0.0%)	0/13 (0.0%)	0/40 (0.0%)	0/76 (0.0%)
Informed consent process deviation	45/272 (16.5%)	1/19 (5.3%)	29/124 (23.4%)	1/13 (7.7%)	2/40 (5.0%)	12/76 (15.8%)
Other	0/272 (0.0%)	0/19 (0.0%)	0/124 (0.0%)	0/13 (0.0%)	0/40 (0.0%)	0/76 (0.0%)

[1] Includes protocol deviations reported by sites for enrolled and screen out participants.

Source: SCHARP (Carolyn) − /trials/hptn/p094/analysis/atlas/code/open/t_deviation_bysite.sas, SAS Version 9.4 (15SEP2025,7:35)

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Listing O5 − Listing of Protocol Deviations

Type of Deviation	Site Name	HIV Cohort	Subject ID	Description of Deviation	Plans and/or Action Taken to Address the Deviation	Plans and/or Action Taken to Prevent Future Occurrences of the Deviation
Lab Assessment Deviation	New York − Bronx Prevention	HIV−	734111562	difficult bloodraw, we were not able to collect plasma for storage for week 52.0	offer participant water to improve hydration	offer participant water to improve hydration
Lab Assessment Deviation	New York − Bronx Prevention	HIV−	734164507	missed fentanyl collection	training in specimen collection v 2.0	review visit coc with lab staff
Lab Assessment Deviation	New York − Bronx Prevention	HIV−	734176355	participant was a difficult blood draw, sample for hepatitis c antibody collected and reported into rave, however sample was insufficient to process hcv rna quantitative pcr according to local lab.	will try to hydrate patient better for next visit	try to hydrate patient better before blood collection
Lab Assessment Deviation	New York − Bronx Prevention	HIV−	734176355	missed fentanyl collection	training in specimen collection v 2.0	review visit coc with lab staff
Lab Assessment Deviation	New York − Bronx Prevention	HIV−	734240489	missed fentanyl collection	training in specimen collection version 2.0	review visit coc with lab staff
Lab Assessment Deviation	New York − Bronx Prevention	HIV−	734319975	unable to get samples for plasma for storage, only samples for serum, dbs and urine were collected	advise patient to hydrate well before visit	offer water to improve hydration before bloodraw
Lab Assessment Deviation	New York − Bronx Prevention	HIV−	734629736	missed fentanyl collection	training in specimen collection under version 2.0	review visit coc with lab staff
Informed Consent Process Deviation	New York − Bronx Prevention	HIV−	734646673	informed consent form stapled incorrectly and two pages misfiled at the office.	informed consent form stapled incorrectly and two pages misfiled at the office. the two pages were re−stapled to the informed consent. corrective action: additional layers of quality control have been added. the staff member who receives the consent form at the site will review the consent form before it is filed and confirm that all the pages are present after it is filed at the site. site staff will be retrained on this process.	corrective action: additional layers of quality control have been added. the staff member who receives the consent form at the site will review the consent form before it is filed and confirm that all the pages are present after it is filed at the site. site staff will be retrained on this process.
Lab Assessment Deviation	New York − Bronx Prevention	HIV−	734713172	this participant came this date for completing his week 26 visit. we were not able to get any blood samples for safety labs and research specimens. he was very dehydrated and after multiple attempts for collecting samples, he decided to come back to complete the blood draw, but he never returned for completing the pending lab procedures	provide hydration in the following visit previous to perform any bloodraw	provide adequate hydration as soon as he shows up for his visit 4.0
Lab Assessment Deviation	New York − Bronx Prevention	HIV−	734723493	missed fentanyl collection and urine for storage	training in specimen collection version 2.0	review visit coc with lab staff
Lab Assessment Deviation	New York − Bronx Prevention	HIV−	734772681	participant was a difficult bloodraw unable to get plasma for storage sample for week 52.0	offer water to participant to improve hydration	offer water to participant to improve hydration

Source: SCHARP (Carolyn) − /trials/hptn/p094/analysis/atlas/code/open/l_deviation.sas, SAS Version 9.4 (15SEP2025,7:35)

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Lab Assessment Deviation	New York − Bronx Prevention	HIV+	734908910	participant was a difficult bloodraw, we were able to collect hepatitis c antibody testing but sample was not sufficient for hcv rna quantitative testing. we were not able to collect plasma and serum for storage	participant was contacted for returning for a new bloodraw. he did not show up.	instruct the patient to drink more water for improving hydration
Lab Assessment Deviation	New York − Bronx Prevention	HIV−	734946601	missed fentanyl collection	training in specimen collection version 2.0. called participant to come back to give sample within window period. he did not return	review visit coc with lab staff
Lab Assessment Deviation	New York − Bronx Prevention	HIV−	734946601	unable to collect samples for research this include plasma, dbs and serum	participant was instructed to hydrate before visit	participant will be offer to drink water to improve hydration
Lab Assessment Deviation	New York − Bronx Prevention	HIV−	734950682	missed fentanyl collection	training in specimen collection v 2.0	review coc with lab staff
Lab Assessment Deviation	New York − Bronx Prevention	HIV−	734984752	participant came to complete week 52 and we were unable to collect blood samples for safety labs and research. we only got enough sample for dbs research specimen	patient counseling about hydration	we will provide sufficient hydration before attempting venipuncture
Lab Assessment Deviation	New York − Bronx Prevention	HIV+	734991131	participant refused collection of urine,rectal and oral swabs at this visit	the participant refused this collection. participation is voluntary and we work with the participant to explain the importance of sti testing for routine health	no further action to be done if a participant does not want to have swabs or urine collected for sti testing
Lab Assessment Deviation	New York − Bronx Prevention	HIV+	734991131	participant was a difficult blood draw unable to obtain labs for protocol visit	participant was instructed to hydrate before visit. patient decline more attempts to obtain samples and prefer to do it at next visit	participant was a difficult blood draw, unpreventable situation.
Lab Assessment Deviation	New York − Bronx Prevention	HIV+	734991131	insufficient sample for viral load testing. laboratory unable to process sample	will advise the participant to keep hydrated previous and during the visit	offer water as soon as the participant shows up to the visit
Informed Consent Process Deviation	Los Angeles − Vine Street		800101290	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Informed Consent Process Deviation	Los Angeles − Vine Street	HIV−	800114552	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.

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Type of Deviation	Site Name	HIV Cohort	Subject ID	Description of Deviation	Plans and/or Action Taken to Address the Deviation	Plans and/or Action Taken to Prevent Future Occurrences of the Deviation
Conduct Of Non−Protocol Procedure	Los Angeles − Vine Street	HIV−	800114552	fentanyl urine testing was performed on week 26 visit	discussed with pi and study regulatory coordinator. plan for avoiding future recurrence discussed. will not be collected at visit 3.0 or visit 4.0.	future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800122566	blood and urine sample not collected at week 52 visit despite multiple attempts due to poor venous access and inadequate hydration. pt did not return 1 week later for sample collection and later lost to follow−up	study staff will reinforce all study required specimens with participants during consent and at each visit	study staff will make every effort to obtain all scheduled specimens during visit and avoid need for split visit. participants will be counseled on optimal hydration while scheduling clinic visits. staff will reach out to participants regularly to schedule specimen collection as the end of their 30 day window approaches.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800143241	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected enrollment visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Informed Consent Process Deviation	Los Angeles − Vine Street		800149499	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800168510	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected enrollment visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.

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Type of Deviation	Site Name	HIV Cohort	Subject ID	Description of Deviation	Plans and/or Action Taken to Address the Deviation	Plans and/or Action Taken to Prevent Future Occurrences of the Deviation
Informed Consent Process Deviation	Los Angeles − Vine Street	HIV−	800171052	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Inappropriate Enrollment	Los Angeles − Vine Street	HIV−	800171052	participant was enrolled/randomized prior to having a second rapid hiv test prior to randomization. the test was performed on the same day of randomization. 7 participants in total were affected by this deviation. all results were concordant with hiv testing during the screening visit. there were no issues with stratification.	none	future participants will have blood collection on the enrollment day prior to randomization. staff will be retrained on on the protocol and ssp specific areas.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800175286	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected enrollment visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Informed Consent Process Deviation	Los Angeles − Vine Street	HIV−	800192054	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800192054	hav igg was ordered but not done by lab.	study staff reviewed proper orders, collection and verification of all scheduled specimens sent to lab at each study visit. staff also counseled to continue to reach out to participant regularly as the end of their study visit or specimen collection window approaches to obtain all necessary study samples	study staff reviewed proper orders, collection and verification of all scheduled specimens sent to lab at each study visit. staff also counseled to continue to reach out to participant regularly as the end of their study visit or specimen collection window approaches to obtain all necessary study samples
Inappropriate Enrollment	Los Angeles − Vine Street	HIV−	800192054	participant was enrolled/randomized prior to having a second rapid hiv test prior to randomization. the test was performed on the same day of randomization. 7 participants in total were affected by this deviation. all results were concordant with hiv testing during the screening visit. there were no issues with stratification.	none	future participants will have blood collection on the enrollment day prior to randomization. staff will be retrained on on the protocol and ssp specific areas.

Source: SCHARP (Carolyn) − /trials/hptn/p094/analysis/atlas/code/open/l_deviation.sas, SAS Version 9.4 (15SEP2025,7:35)

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Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800192965	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected enrollment visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800192965	week 52 hcv rna pcr was collected but lab reported sample not received for this test	study staff reviewed proper collection and verification of all scheduled specimens sent to lab at each study visit. unable to obtain additional specimen due to participant termination/planned study end	study staff reviewed proper collection and verification of all scheduled specimens sent to lab at each study visit. unable to obtain additional specimen due to participant termination/planned study end
Lab Assessment Deviation	Los Angeles − Vine Street	HIV+	800246969	the dry blood spot specimen was not a requirement for participants living with hiv but was inadvertently collected during the enrollment visit	all study staff were counseled on proper specimen collection and study procedures at each visit, particularly the differences in specimen collection for participants living with and without hiv. protocol lead team (hptn loc, scharp sdmc, hptn nl)located the dried blood (dbs) specimen − the specimen was not stored and marked as destroyed by ldms lab 194	all study staff were counseled on proper specimen collection and study procedures at each visit, particularly the differences in specimen collection for participants living with and without hiv. there have been no further incidents after this enrollment visit.
Conduct Of Non−Protocol Procedure	Los Angeles − Vine Street	HIV+	800246969	participant presented for wk 26 visit on 06/jun/2023 but needed to leave for another medical appt after completing behavioral questionnaires part a and b only. no other study procedures completed, including specimen and data collection on 06/jun/2023. the participant then resumed the completion of the wk 26 visit, including all related study procedures and data collection on 08/jun/2023. this split visit resulted in a navigation session performed 2 days after the initial wk 26 visit date.	all study staff was counseled on scheduling study visits on days where participant is available for appropriate duration to complete all study procedures and data collection in their entirety. emphasis was made in minimizing/reserving split visits only for specimen collection of blood and/or urine due to difficult venous access/inadequate hydration issues.	all study staff was counseled on scheduling study visits on days where participant is available for appropriate duration to complete all study procedures and data collection in their entirety. emphasis was made in minimizing/reserving split visits only for specimen collection of blood and/or urine due to difficult venous access/inadequate hydration issues.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV+	800246969	participant presented for wk 26 visit on 06/jun/2023 but needed to leave for another medical appt after completing behavioral questionnaires part a and b only. no other study procedures completed, including specimen and data collection on 06/jun/2023. the participant then resumed the completion of the wk 26 visit, including all related study procedures and data collection on 08/jun/2023. this split visit resulted in specimen collection performed 2 days after the initial wk 26 visit date.	all study staff was counseled on scheduling study visits on days where participant is available for appropriate duration to complete all study procedures and data collection in their entirety. emphasis was made in minimizing/reserving split visits only for specimen collection of blood and/or urine due to difficult venous access/inadequate hydration issues.	all study staff was counseled on scheduling study visits on days where participant is available for appropriate duration to complete all study procedures and data collection in their entirety. emphasis was made in minimizing/reserving split visits only for specimen collection of blood and/or urine due to difficult venous access/inadequate hydration issues.

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Conduct Of Non−Protocol Procedure	Los Angeles − Vine Street		800255884	individual was seen for enrollment visit (ultimately did not enroll) on 9/8/2022 which was beyond the 30−day window of screening. this occurred due to split screen. split screen visit 1 of 2 was on 8/2/2022 and split screen visit 2 of 2 was on 8/18/2022. clinician interpreted screening window to be 30 days from split screen visit 2 of 2.	none, individual was ultimately screen failed.	for screening windows of 30−days will be counted from date of consent, in the event that screening is split.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800258388	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected enrollment visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Informed Consent Process Deviation	Los Angeles − Vine Street	HIV−	800275854	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Conduct Of Non−Protocol Procedure	Los Angeles − Vine Street	HIV−	800275854	fentanyl urine testing was performed on week 26 visit	discussed with pi and study regulatory coordinator. plan for avoiding future recurrence discussed. will not be collected at visit 3.0 or visit 4.0.	future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800292058	gc/ct throat swab was not collected due to order omission by clinician.	study staff reviewed and counseled on proper orders and collection of all scheduled specimens during each study visit. staff will continue to reach out to participant regularly as the end of their study visit window approaches	study staff reviewed and counseled on proper orders and collection of all scheduled specimens during each study visit.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800301182	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected enrollment visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.

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Type of Deviation	Site Name	HIV Cohort	Subject ID	Description of Deviation	Plans and/or Action Taken to Address the Deviation	Plans and/or Action Taken to Prevent Future Occurrences of the Deviation
Informed Consent Process Deviation	Los Angeles − Vine Street	HIV+	800312871	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Conduct Of Non−Protocol Procedure	Los Angeles − Vine Street	HIV+	800312871	fentanyl urine testing was performed on week 26 visit	discussed with pi and study regulatory coordinator. plan for avoiding future recurrence discussed. will not be collected at visit 3.0 or visit 4.0.	future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV+	800312871	he dry blood spot specimen was not a requirement for participants living with hiv but was inadvertently collected during this week 26 visit	all study staff were counseled on proper specimen collection and study procedures at each visit, particularly the differences in specimen collection for participants living with and without hiv. protocol lead team (hptn loc, scharp sdmc, hptn nl) will provide guidance on status determination of collected and stored specimen	all study staff were counseled on proper specimen collection and study procedures at each visit, particularly the differences in specimen collection for participants living with and without hiv.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800330032	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected enrollment visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800330032	participant week 26 visit urine for gc/ct was collected but cancelled by lab due to deficient quantity.	study staff will reinforce all study visit requirements including study visit windows and specimen requirements during consent and at each study visit	participants will be counseled on optimal hydration while scheduling visits. staff will reach out to participants regularly as the end of their study window approaches
Informed Consent Process Deviation	Los Angeles − Vine Street	HIV−	800333849	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.

Source: SCHARP (Carolyn) − /trials/hptn/p094/analysis/atlas/code/open/l_deviation.sas, SAS Version 9.4 (15SEP2025,7:35)

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Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800334902	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected enrollment visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800346664	week 26 fentanyl testing not performed	all study staff were updated of the changes to protocol − version 2.0 particularly in the change requiring additional lab assessments including fentanyl testing	all study staff to be updated of protocol changes, particularly in changes requiring additional lab assessments and study procedures in a more timely manner
Inappropriate Enrollment	Los Angeles − Vine Street	HIV−	800350782	enrollment coincided with release and approval of protocol version 2.0, which included a new enrollment criteria, that urine positive for methadone is an exclusion criteria. site−level icf was approved 21apr2023. but protocol signature page was not signed until 2	training with full team on new enrollment criteria was done on 28apr2023.	new versions of enrollment crf have been posted in electronic medical record.
Informed Consent Process Deviation	Los Angeles − Vine Street	HIV−	800350843	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800350843	hepatitis a virus antibody (hav total) ordered but inadvertently not performed.	study staff reviewed proper orders, collection and verification of all scheduled specimens sent to lab at each study visit. staff also counseled to continue to reach out to participant regularly as the end of their study visit or specimen collection window approaches to obtain all necessary study samples	study staff reviewed proper orders, collection and verification of all scheduled specimens sent to lab at each study visit. staff also counseled to continue to reach out to participant regularly as the end of their study visit or specimen collection window approaches to obtain all necessary study samples
Inappropriate Enrollment	Los Angeles − Vine Street	HIV−	800350843	participant was enrolled/randomized prior to having a second rapid hiv test prior to randomization. the test was performed on the same day of randomization. 7 participants in total were affected by this deviation. all results were concordant with hiv testing during the screening visit. there were no issues with stratification.	none	future participants will have blood collection on the enrollment day prior to randomization. staff will be retrained on on the protocol and ssp specific areas.

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Conduct Of Non−Protocol Procedure	Los Angeles − Vine Street	HIV−	800350843	fentanyl urine testing was performed on week 26 visit	discussed with pi and study regulatory coordinator. plan for avoiding future recurrence discussed. will not be collected at visit 3.0 or visit 4.0.	future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800350843	hiv lab specimen was collected on 52−week visit date on 7/25/2022 but not run. by laboratory. gc/ct testing was also collected and not run. this occurred due to rerouting or labeling problem with specimen.	attempted to bring in participant for repeat draw within 52−week visit window. contact attempts included phone, text messages as well as physical visit at participant home address. participant made contact with mobile unit staff on 10/12/2022. study staff requested guidance from cmc. cmc approved conducting outstanding lab work outside of visit window.	crs lab manager, clinician, and ma had a meeting on 8/19/2022 with research lab to discuss gap in workflow and prevent future missed procedures.
Conduct Of Non−Protocol Procedure	Los Angeles − Vine Street	HIV−	800350843	fentanyl urine testing was performed on week 52 visit	discussed with pi and study regulatory coordinator. plan for avoiding future recurrence discussed. will not be collected at visit 3.0 or visit 4.0.	future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Unreported Sae	Los Angeles − Vine Street	HIV−	800358592	the hospitalization/sae that participant informed study site of on 5/15/2024 via phone was reported by study site outside of protocol defined window	sae was reported and protocol deviation filed by study site. all study staff counseled on sae reporting guidelines, including sae criteria, sae associated pertinent data collection, sae reported timeframes per protocol.	all study staff counseled on sae reporting guidelines, including sae criteria, associated sae pertinent data collection, and sae reporting timeframes per study protocol.
Conduct Of Non−Protocol Procedure	Los Angeles − Vine Street	HIV−	800376234	fentanyl urine testing was performed on week 26 visit	discussed with pi and study regulatory coordinator. plan for avoiding future recurrence discussed. will not be collected at visit 3.0 or visit 4.0.	future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800376234	hcv rna was not collected due to omission by clinician.	clinician has left team.	clinician has left team.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800380536	blood for storage and future research not obtained at screening visit due to participant poor venous access.	study staff counseled to reinforce all study specimen requirements during consent and at each study visit	study staff counseled to make every effort to obtain all study specimens during study visit and avoid the need for split visits. participants will be counseled on optimal hydration while scheduling study visits. staff will reach out to participants regularly as the end of their study collection window closes.

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Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800380536	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected enrollment visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Conduct Of Non−Protocol Procedure	Los Angeles − Vine Street	HIV−	800380536	fentanyl urine testing was performed on week 26 visit	discussed with pi and study regulatory coordinator. plan for avoiding future recurrence discussed. will not be collected at visit 3.0 or visit 4.0.	future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800380536	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected 26−week visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Conduct Of Non−Protocol Procedure	Los Angeles − Vine Street	HIV−	800380536	visit was performed outside of visit window per loa 02/jun/2023 d/t change from allowable visit window for week 52 from until the study is closed at the site to day 449	counseled all staff on new max allowable visit window end for week 52 visit is day 449 per loa 02/jun/2023. study staff will reinforce all study visit requirements including study visit windows and specimen requirements during informed consent and at each study visit	counseled all staff on new max allowable visit window end for week 52 visit is day 449, per loa 02/jun/2023. study staff will reach out to participants regularly as the end of their study visit window approaches
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800393737	hep c test was not performed as part of week−26 visit. we contacted the participant on a later date to conduct the hep c test but they declined.	we attempted to schedule the hep c test once we became aware that the test had not been conducted at the week−26−visit.	all clinicians have been reminded to conduct hep c testing at the week−26 visit.
Informed Consent Process Deviation	Los Angeles − Vine Street		800407103	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.

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Informed Consent Process Deviation	Los Angeles − Vine Street		800422442	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Informed Consent Process Deviation	Los Angeles − Vine Street		800432344	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800487711	week 52 visit hcv rna pcr was collected but subsequently cancelled by lab due to qns	study staff will reinforced all study required specimens during consent and at each visit	participants will be counseled on optimal hydration while scheduling visits. staff will reach out to participants regularly as the end of their 30 day window approaches. study staff will not discontinue/terminate participant in medidata until all required specimens are collected or the 30 day threshold from week 52 visit has been reached
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800497470	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected enrollment visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800497470	hcv rna pcr specimen was not collected due to omission by clinician	recall efforts for specimen collection unsuccessful. study staff reviewed proper orders and collection of all scheduled specimens during each study visit. staff reminded to continue to reach out to participant regularly as the end of their specimen collection window approaches.	study staff reviewed proper orders and collection of all scheduled specimens during each study visit. staff reminded to continue to reach out to participant regularly as the end of their specimen collection window approaches.
Unreported Sae	Los Angeles − Vine Street	HIV−	800499976	the sae occurrence that participant informed study site of during 3/28/24 week 52 visit was reported by study site outside of protocol defined window	sae was reported and protocol deviation filed by study site. all study staff counseled on sae reporting guidelines, including sae criteria, sae associated pertinent data collection, and sae reporting timeframes per study protocol	all study staff counseled on sae reporting guidelines, including sae criteria, sae associated pertinent data collection, and sae reporting timeframes per study protocol

Source: SCHARP (Carolyn) − /trials/hptn/p094/analysis/atlas/code/open/l_deviation.sas, SAS Version 9.4 (15SEP2025,7:35)

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Informed Consent Process Deviation	Los Angeles − Vine Street		800502805	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800509445	plasma, dry blood spot and serum samples for storage not collected due to participant poor venous access.	study staff counseled to remind participants of optimal hydration while scheduling visits. participant unable to return for split visit collection within window	study staff counseled to remind participants of optimal hydration while scheduling visits. study staff will reach out to participants regularly as the end of their visit or specimen collection window approaches to obtain all necessary study samples.
Conduct Of Non−Protocol Procedure	Los Angeles − Vine Street	HIV−	800509445	fentanyl urine testing was performed on week 26 visit	discussed with pi and study regulatory coordinator. plan for avoiding future recurrence discussed. will not be collected at visit 3.0 or visit 4.0.	future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800517042	hcv rna pcr quant specimen collected was not run by lab.	participant was contact in subsequent weeks, documented in redcap to bring back for re−draw. study team was unable to bring back for re−draw. he is now incarcerated.	continue to attempt to draw specimens with sufficient quantity.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800522256	week 26 visit hcv rna pcr was collected but cancelled by lab due to quantity not sufficient. unable to recall participant for additional specimen despite multiple attempts − unresponsive to contact efforts	study staff will reinforce all study required procedures including the collection of necessary specimens during consent and at each study visit	participants will be counseled on optimal hydration while scheduling visits. study staff will reach out to participants regularly as the end of their visit or specimen collection window approaches
Informed Consent Process Deviation	Los Angeles − Vine Street	HIV−	800555559	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800555559	enrollment urine drug screen, pregnancy test, chlamydia/gonorrhea testing and urine for storage were not run as participant was not able to produce urine during the enrollment visit. we requested for her to return within the allowable 10−day time frame but she did not return to give sample.	will encourage hydration for subsequent study visits.	will encourage hydration prior to collection of enrollment labs.

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Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800555559	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected 26−week visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Conduct Of Non−Protocol Procedure	Los Angeles − Vine Street	HIV−	800555559	fentanyl urine testing was performed on week 26 visit	discussed with pi and study regulatory coordinator. plan for avoiding future recurrence discussed. will not be collected at visit 3.0 or visit 4.0.	future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800555559	quantity insufficient specimen draw for serum storage due to difficult venous access.	study staff will continue to encourage participant to return for phlebotomy re−attempt within the visit window.	at 52 week visit, will consider having participant come to crs for alternate staff to attempt phlebotomy.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800567746	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected enrollment visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800567746	hep c test was not performed as part of the retention visit. we were able to schedule and conduct the hep c test after the retention visit took place.	we scheduled and conducted the hep c test once we became aware that the test had not been conducted at the retention visit.	the clinician who omitted the test is no longer with the study team. all clinicians have been reminded to conduct hep c testing at the retention visits
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800574395	hep c test was not performed as part of the retention visit. we attempted to schedule the appointment at a later date following the retention visit but were not able to do so.	we attempted to schedule the hep c test once we became aware that the test had not been conducted at the retention visit.	the clinician who omitted the test is no longer with the study team. all clinicians have been reminded to conduct hep c testing at the retention visits.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800592688	enrollment hcv rna pcr quant specimen was collected but not run by lab due to quantity not sufficient	study staff counseled to reinforce with participant all study required procedures including collection of necessary study specimens which may necessitate repeat specimen collection as needed, during consent and at each study visit	study staff counseled to remind participants of optimal hydration while scheduling visits. study staff will reach out to participants regularly as the end of their visit or specimen collection window approaches to obtain all necessary study samples.

Source: SCHARP (Carolyn) − /trials/hptn/p094/analysis/atlas/code/open/l_deviation.sas, SAS Version 9.4 (15SEP2025,7:35)

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Type of Deviation	Site Name	HIV Cohort	Subject ID	Description of Deviation	Plans and/or Action Taken to Address the Deviation	Plans and/or Action Taken to Prevent Future Occurrences of the Deviation
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800597220	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected enrollment visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Informed Consent Process Deviation	Los Angeles − Vine Street	HIV−	800621114	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Conduct Of Non−Protocol Procedure	Los Angeles − Vine Street	HIV−	800621114	fentanyl urine testing was performed on week 26 visit	discussed with pi and study regulatory coordinator. plan for avoiding future recurrence discussed. will not be collected at visit 3.0 or visit 4.0.	future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Conduct Of Non−Protocol Procedure	Los Angeles − Vine Street	HIV−	800650520	visit was performed outside of visit window per loa 02/jun/2023 due to change for allowable visit window for week 52 from until the study is closed at site to day 449	counseled all staff on new max allowable visit window end for week 52 visit is day 449 per loa 02/jun/2023. study staff will reinforce all study visit requirements including study visit windows and specimen requirements during informed consent and at each study visit.	counseled all staff on new max allowable visit window end for week 52 visit is day 449 per loa 02/jun/2023. staff will reach out to participants regularly as the end of their study visit window approaches.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800651352	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected enrollment visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Conduct Of Non−Protocol Procedure	Los Angeles − Vine Street	HIV−	800651352	fentanyl urine testing was performed on week 26 visit	discussed with pi and study regulatory coordinator. plan for avoiding future recurrence discussed. will not be collected at visit 3.0 or visit 4.0.	future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.

Source: SCHARP (Carolyn) − /trials/hptn/p094/analysis/atlas/code/open/l_deviation.sas, SAS Version 9.4 (15SEP2025,7:35)

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Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800651352	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected 26−week visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800651352	hep c test was not performed as part of the retention visit. we attempted to schedule the appointment at a later date following the retention visit but were not able to do so.	we attempted to schedule the hep c test once we became aware that the test had not been conducted at the retention visit.	the clinician who omitted the test is no longer with the study team. all clinicians have been reminded to conduct hep c testing at the retention visit.
Conduct Of Non−Protocol Procedure	Los Angeles − Vine Street	HIV−	800667864	fentanyl urine testing was performed on week 26 visit	discussed with pi and study regulatory coordinator. plan for avoiding future recurrence discussed. will not be collected at visit 3.0 or visit 4.0.	future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800667864	hcv rna pcr quant specimen collected was not run by lab for quantity nonsufficient	none; participant was discontinued for planned study exit and was referred for hcv care.	continue to attempt to collect sufficient specimen quantity on difficult draws. crs lab manager working with performing lab on improving processes.
Informed Consent Process Deviation	Los Angeles − Vine Street	HIV−	800677155	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Inappropriate Enrollment	Los Angeles − Vine Street	HIV−	800677155	participant was enrolled/randomized prior to having a second rapid hiv test prior to randomization. the test was performed on the same day of randomization. 7 participants in total were affected by this deviation. all results were concordant with hiv testing during the screening visit. there were no issues with stratification.	none	future participants will have blood collection on the enrollment day prior to randomization. staff will be retrained on on the protocol and ssp specific areas.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800677155	storage specimens were not collected for 26−week visit due to poor venous access. missing hiv laboratory testing result.	study staff will continue to encourage participant to return for specimen draw re−attempt within visit window.	vein finder device planned to be used for facilitation of phlebotomy at week 52 visit.

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Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800677155	syphilis testing was not performed at week 26 visit due to poor venous access	study staff reviewed/counseled on proper orders and collection of all scheduled study specimens at each study visit. recall attempts unsuccessful. participants will be counseled on optimal hydration while scheduling clinic visits. staff counseled to reach out to participant regularly for recall as the end of their specimen collection window approaches	study staff reviewed/counseled on proper orders and collection of all scheduled study specimens at each study visit. recall attempts unsuccessful. participants will be counseled on optimal hydration while scheduling clinic visits. staff counseled to reach out to participant regularly for recall as the end of their specimen collection window approaches
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800677155	hepatitis/hiv/rpr/blood for storage and future research not performed as blood not collected at week 52 visit due to participant poor venous access. pt did not return for sample collection despite multiple attempts − unable to contact participant	study staff will reinforce all study required specimens with participants during consent and at each visit	study staff will make every effort to obtain all scheduled specimens during visit and avoid need for split visit. participants will be counseled on optimal hydration while scheduling clinic visits. staff will reach out to participants regularly as the end of their study visit and specimen collection window approaches.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800730730	the participant declined consent for samples of blood and urine for long−term storage/future research with participant unable to present within study visit window for collection, therefore blood and urine were subsequently not stored at the screening visit.	all study staff were counseled the specimens of participants who do not consent to long−term storage and additional testing will be destroyed at the end of the study after protocol−related testing has been completed, at least one one year after completion of the primary manuscript. a list of samples to be destroyed will be provided by the sdmc, to be reviewed and reconciled by the site. final approval for sample destruction will be provided in writing to the site by the lc per study protocol	all study staff were counseled the specimens of participants who do not consent to long−term storage and additional testing will be destroyed at the end of the study after protocol−related testing has been completed, at least one one year after completion of the primary manuscript. a list of samples to be destroyed will be provided by the sdmc, to be reviewed and reconciled by the site. final approval for sample destruction will be provided in writing to the site by the lc per study protocol
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800730730	the participant declined consent for samples of blood and urine for long−term storage/future research with participant unable to present within study visit window for collection, therefore blood and urine were subsequently not stored at the enrollment visit.	all study staff were counseled the specimens of participants who do not consent to long−term storage and additional testing will be destroyed at the end of the study after protocol−related testing has been completed, at least one one year after completion of the primary manuscript. a list of samples to be destroyed will be provided by the sdmc, to be reviewed and reconciled by the site. final approval for sample destruction will be provided in writing to the site by the lc per study protocol	all study staff were counseled the specimens of participants who do not consent to long−term storage and additional testing will be destroyed at the end of the study after protocol−related testing has been completed, at least one one year after completion of the primary manuscript. a list of samples to be destroyed will be provided by the sdmc, to be reviewed and reconciled by the site. final approval for sample destruction will be provided in writing to the site by the lc per study protocol
Conduct Of Non−Protocol Procedure	Los Angeles − Vine Street	HIV−	800747896	fentanyl urine testing was performed on week 26 visit	discussed with pi and study regulatory coordinator. plan for avoiding future recurrence discussed. will not be collected at visit 3.0 or visit 4.0.	future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.

Source: SCHARP (Carolyn) − /trials/hptn/p094/analysis/atlas/code/open/l_deviation.sas, SAS Version 9.4 (15SEP2025,7:35)

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Type of Deviation	Site Name	HIV Cohort	Subject ID	Description of Deviation	Plans and/or Action Taken to Address the Deviation	Plans and/or Action Taken to Prevent Future Occurrences of the Deviation
Informed Consent Process Deviation	Los Angeles − Vine Street	HIV−	800755159	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Conduct Of Non−Protocol Procedure	Los Angeles − Vine Street	HIV−	800755159	fentanyl urine testing was performed on week 26 visit	discussed with pi and study regulatory coordinator. plan for avoiding future recurrence discussed. will not be collected at visit 3.0 or visit 4.0.	future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800755159	storage specimens were not collected for 26−week visit due to poor venous access.	encourage return to participants for split visits during 26 week window for reattempt at phlebotomy.	encourage return to participants for split visits during 26 week window for reattempt at phlebotomy.
Inappropriate Enrollment	Los Angeles − Vine Street	HIV−	800769864	participant was enrolled/randomized prior to having a second rapid hiv test prior to randomization. the test was performed on the same day of randomization. 7 participants in total were affected by this deviation. all results were concordant with hiv testing during the screening visit. there were no issues with stratification.	none	future participants will have blood collection on the enrollment day prior to randomization. staff will be retrained on on the protocol and ssp specific areas.
Informed Consent Process Deviation	Los Angeles − Vine Street	HIV−	800769864	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800769864	dry blood spot and serum specimen for storage not collected at week 26 visit due to poor venous access.	study staff reviewed/counseled on proper orders and collection of all scheduled study specimens at each study visit. participants will be counseled on optimal hydration while scheduling clinic visits. staff counseled to reach out to participant regularly for recall as the end of their specimen collection window approaches.	study staff reviewed/counseled on proper orders and collection of all scheduled study specimens at each study visit. participants will be counseled on optimal hydration while scheduling clinic visits. staff counseled to reach out to participant regularly for recall as the end of their specimen collection window approaches.

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Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800769864	fentanyl urine testing was performed on week 26 visit	discussed with pi and study regulatory coordinator. plan for avoiding future recurrence discussed. will not be collected at visit 3.0 or visit 4.0.	future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800769864	hcv rna was not run by lab	emailed lab on january 3, 2022. we were told it was because labels were not printed for the specific lab.	ma was trained to print out all labels so all labs can be run.
Informed Consent Process Deviation	Los Angeles − Vine Street		800770443	half of the signature on eicf was not captured due to limitations of the signature box.	staff was trained when collecting eicf signature to instruct participant to enter signature within box, and verify that the entire signature is in the box.	staff was trained when collecting eicf signature to instruct participant to enter signature within box, and verify that the entire signature is in the box.
Informed Consent Process Deviation	Los Angeles − Vine Street		800770443	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Informed Consent Process Deviation	Los Angeles − Vine Street		800786492	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Informed Consent Process Deviation	Los Angeles − Vine Street	HIV−	800811476	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Inappropriate Enrollment	Los Angeles − Vine Street	HIV−	800811476	participant was enrolled/randomized prior to having a second rapid hiv test prior to randomization. the test was performed on the same day of randomization. 7 participants in total were affected by this deviation. all results were concordant with hiv testing during the screening visit. there were no issues with stratification.	none	future participants will have blood collection on the enrollment day prior to randomization. staff will be retrained on on the protocol and ssp specific areas.

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Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800813298	hep c test was not performed as part of the retention visit. we attempted to schedule the appointment at a later date following the retention visit but were not able to do so.	we attempted to schedule the hep c test once we became aware that the test had not been conducted at the retention visit.	the clinician who omitted the test is no longer with the study team. all clinicians have been reminded to conduct hep c testing at the retention visits.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800819179	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected enrollment visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800819179	hcv rna pcr quant specimen collected was not run by lab due to qns	study staff counseled to reinforce with participant all study required procedures including collection of necessary study specimens which may necessitate repeat specimen collection as needed, during consent and at each study visit	study staff counseled to remind participants of optimal hydration while scheduling visits. study staff will reach out to participants regularly as the end of their visit or specimen collection window approaches to obtain all necessary study samples.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800840873	hepatitis c quantitative pcr not performed at week 26 visit due to inadvertent clinician omission	study staff reviewed and counseled on proper orders and collection of all scheduled specimens at each study visit. staff will continue to reach out to participant regularly as the end of their specimen visit window approaches	study staff reviewed and counseled on proper orders and collection of all scheduled specimens during each study visit.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800867887	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected enrollment visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Conduct Of Non−Protocol Procedure	Los Angeles − Vine Street	HIV−	800867887	fentanyl urine testing was performed on week 26 visit	discussed with pi and study regulatory coordinator. plan for avoiding future recurrence discussed. will not be collected at visit 3.0 or visit 4.0.	future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.

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Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800867887	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected 26−week visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Conduct Of Non−Protocol Procedure	Los Angeles − Vine Street	HIV−	800867887	at 26−week visit, control arm study participant was treated for chlamydia that was diagnosed on enrollment. 26−week labs returned positive syphilis, study staff presented case to protocol team at site/crs call. guidance was received to treat participant. study team treated participant on 8/31/2022 with bicillin la injection.	discussed with protocol team at following site visit/network call. protocol deviation filed.	protocol team released bulletin clarifying treatment for sti on week 26 visit labs. control arm participants will continue to be referred to community provider only.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800867887	week 52 fentanyl testing not performed	all study staff were updated of the changes to protocol− version 2 particularly in the change requiring additional lab assessments including fentanyl testing	all study staff to be updated of protocol changes, particularly in changes requiring additional lab assessments in a more timely manner
Informed Consent Process Deviation	Los Angeles − Vine Street		800905645	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Informed Consent Process Deviation	Los Angeles − Vine Street		800907461	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800909267	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected enrollment visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.

Source: SCHARP (Carolyn) − /trials/hptn/p094/analysis/atlas/code/open/l_deviation.sas, SAS Version 9.4 (15SEP2025,7:35)

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Type of Deviation	Site Name	HIV Cohort	Subject ID	Description of Deviation	Plans and/or Action Taken to Address the Deviation	Plans and/or Action Taken to Prevent Future Occurrences of the Deviation
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800914630	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected enrollment visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800914630	hcv rna was not resulted as qns	n/a	hydrate participants prior to blood draws
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800914630	blood sample not performed at week 52 visit due to slow venous access. pt did not return for sample collection despite multiple contacts	study staff will reinforce all study required specimens with participant during consent and at each visit.	study staff will make every effort to obtain all scheduled specimens during visit and avoid need for split visit. participants will be counseled on optimal hydration while scheduling clinic visits. staff will reach out to participants regularly as the end of their 30 day window approaches
Informed Consent Process Deviation	Los Angeles − Vine Street	HIV−	800920484	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Informed Consent Process Deviation	Los Angeles − Vine Street		800950297	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800953096	hepatitis/hiv/rpr/blood for storage and future research not performed as blood not collected at week 26 visit due to participant poor venous access. pt did not return for sample collection despite multiple attempts − unable to contact participant	study staff will reinforce all study required specimens with participants during consent and at each visit	study staff will make every effort to obtain all scheduled specimens during visit and avoid need for split visit. participants will be counseled on optimal hydration while scheduling clinic visits. staff will reach out to participants regularly as the end of their study visit and specimen collection window approaches.

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Informed Consent Process Deviation	Los Angeles − Vine Street		800957982	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Informed Consent Process Deviation	Los Angeles − Vine Street	HIV−	800958830	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800959390	hcv rna pcr specimen not collected at week 26 visit.	study staff reviewed proper orders and collection of all scheduled specimens during each study visit. staff reminded to continue to reach out to participant regularly as the end of their specimen collection window approaches.	study staff reviewed proper orders and collection of all scheduled specimens during each study visit. staff reminded to continue to reach out to participant regularly as the end of their specimen collection window approaches.
Lab Assessment Deviation	Los Angeles − Vine Street	HIV−	800959390	urine sample for gc/ct not collected. pt unable to provide sample at week 52 visit. pt did not return for sample collection despite multiple contact attempts	study staff will reinforce all study required specimens with participants on consent and at each visit	study staff will make every effort to obtain all scheduled specimens during visit and avoid need for split visit. staff will reach out to participants regularly to schedule specimen collection as the end of their 30 day window approaches. study staff will not discontinue/terminate participant from study in medidata until all required visit specimens are obtained or the 30 day threshold from week 52 visit is reached.
Informed Consent Process Deviation	Los Angeles − Vine Street	HIV−	800966895	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Inappropriate Enrollment	Los Angeles − Vine Street	HIV−	800966895	participant was enrolled/randomized prior to having a second rapid hiv test prior to randomization. the test was performed on the same day of randomization. 7 participants in total were affected by this deviation. all results were concordant with hiv testing during the screening visit. there were no issues with stratification.	none	future participants will have blood collection on the enrollment day prior to randomization. staff will be retrained on on the protocol and ssp specific areas.

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Lab Assessment Deviation	Washington DC − Washington Circle	HIV−	801162606	procedures related to primary endpoints of the study (lab−based hiv testing, plasma storage, and dbs storage) were not completed. participant presented for their week 26 visit on 25jul23. due to difficult venous access, the clinician was unable to collect blood. all other study visit procedures were completed. we planned to conduct a split visit to complete the blood draw later that week, but we had to cancel due to mobile unit mechanical issues. staff attempted to reschedule, but the participant never returned, and the visit window has now closed.	staff made numerous unsuccessful attempts to schedule a split visit.	staff will continue to make every attempt to complete all visit procedures on the same day.
Lab Assessment Deviation	Washington DC − Washington Circle	HIV−	801351654	the hiv testing algorithm was not followed as per protocol. participant presented for week 26 on 17dec21. multiple unsuccessful attempts were made to draw enough blood for all of the required lab tests. we planned to conduct a split visit to complete the remaining assessments on another day, but he never returned and the visit window has now closed. as a result, blood could not be collected for lab−based hiv testing, in addition to other testing (heme/chem testing, hepatitis testing, sti testing, and serum storage for sars−cov−2 testing).	staff made numerous unsuccessful attempts to schedule a split visit. we offered to meet the participant at different locations to make it more convenient for him to return to the mobile unit.	we will continue to make every attempt to complete all visit procedures on the same day. this participant consented to allow home visits and we will offer this as an option for his week 52 visit.
Conduct Of Non−Protocol Procedure	Washington DC − Washington Circle	HIV−	801405979	participant contacted site on 15jul22 because she was having trouble refilling iron and moud prescriptions. the navigator called the participant's provider on her behalf to refill her prescriptions. additionally, the navigator suggested that the participant contact one of the satellite offices of a clinic and they advised her on what to say when she called.	the team met to discuss post−week 26 visit navigation regarding what is permitted and not permitted. peer navigators were re−trained on navigation after the week 26 visit.	the ior, navigation supervisor and team will have continued discussions to ensure that navigation is not provided after the week 26 visit.
Lab Assessment Deviation	Washington DC − Washington Circle	HIV−	801405979	due to difficult venous access, we were not able to collect a serum storage sample at the week 52 visit.	the participant did not return for a redraw despite site attempts. the hptn lc was notified on 01dec22. we are reporting this as a protocol deviation now per scharp guidance.	n/a (site no longer has participants in study follow−up)
Conduct Of Non−Protocol Procedure	Washington DC − Washington Circle	HIV−	801466938	on 18aug22, the participant contacted the peer navigator because he was having difficulty with his moud appointment. the peer navigator contacted other moud providers on behalf of the participant to get them connected to moud immediately. ultimately, the peer navigator scheduled a moud appointment for the participant, and they helped the participant receive a bridge prescription for moud.	the team met to discuss post week 26 visit navigation regarding what is permitted and not permitted. peer navigators were re−trained on navigation after the week 26 visit.	the ior, navigation supervisor, and team will have continued discussions to ensure that navigation is not provided after the week 26 visit.

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Lab Assessment Deviation	Washington DC − Washington Circle	HIV+	801516175	a procedure related to primary endpoints was not completed. the participant presented for their week 26 visit on 21feb24. due to difficult venous access and despite multiple blood draw attempts, the study clinician was only able to collect enough blood to complete hiv and hcv viral load and syphilis testing. as a result, blood was not able to be collected for plasma storage at week 26. all other study visit procedures except serum storage were completed. after multiple blood draw attempts, the study clinician did not believe that the participant should return for an additional draw attempt.	the study clinician attempted multiple times to draw enough blood for all required labs.	staff will continue to make every attempt to complete all visit procedures.
Informed Consent Process Deviation	Washington DC − Washington Circle	HIV−	801740612	participant 801−74061−2 had their week 26 visit on 30mar23. the informed consent form compensation addendum contained information about the updated incentive structure, including the week 26 visit compensation changing from $85 to $100. there are no study procedures listed on the updated icf addendum; this document only covers the increased incentive amounts. this error resulted in the participant receiving $15 extra beyond the original expectation. study staff did not realize the oversight until 06apr23 at which point the site pis were immediately notified.	study staff are working to schedule 801−74061−2 to return to the mobile unit as soon as possible to sign the informed consent compensation addendum.	study staff were re−trained on systems already in place to prevent a missed reconsent on 06apr23. additionally, the site will add language to the clinical care/interim visit and week 26/52 visit checklists to remind staff to confirm if a participant has signed the most recent version of the informed consent form. the study staff will also add ˆreconsentˆ to calendar entries when they schedule a visit for a participant who needs to sign the most recent version of the informed consent form or an addendum.
Lab Assessment Deviation	Washington DC − Washington Circle	HIV−	801746123	procedures related to primary endpoints were not completed. the participant presented for their week 26 visit on 14feb24. after four blood draw attempts, the study clinician was only able to collect enough blood to complete lab−based hiv testing. as a result, blood was not collected for plasma and dbs storage. all study visit procedures not dependent on blood collection were completed. due to extremely challenging venous access, the study clinician did not believe that the participant should return for an additional draw attempt, given that this would be very unlikely to result in success.	the study clinician made four attempts to draw enough blood for all required labs.	staff will continue to make every attempt to complete all visit procedures.
Lab Assessment Deviation	Washington DC − Washington Circle	HIV−	801832366	due to the participant’s inability to void enough urine, the site could not collect a urine storage sample at the week 52 visit.	the participant was terminated and a sample can no longer be collected. we are reporting this as a protocol deviation now per scharp guidance.	n/a (site no longer has participants in study follow−up).
Lab Assessment Deviation	Washington DC − Washington Circle	HIV+	801926387	due to difficult venous access, the site could not collect a serum storage sample at the participant’s week 52 visit.	the participant was terminated and a sample can no longer be collected. we are reporting this now as a protocol deviation per scharp guidance.	n/a (site no longer has participants in study follow−up).

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Lab Assessment Deviation	Washington DC − Washington Circle	HIV−	801943631	participant enrolled on 28feb23 and completed all required testing, but hav ab and hbv testing were not performed by the local testing lab due to ˆinsufficient specimen˜. all required tubes of blood were drawn at the visit, sent to the site processing lab, prepared and sent with the required tests on the requisition form to the local testing lab. all required storage samples were accounted for and logged into ldms. upon receipt of the lab results on 04mar23, the site learned the local testing lab had not performed hav ab and hbv testing, despite being sent an appropriate amount of specimen	site attempted to get the participant to return to complete the hav and hbv testing within 30 days of enrollment (28feb23). the participant did not return until their clinical care visit 203.0 on 11apr23. the hav ab/hbv tests were performed at that time. based on protocol bulletin #12 and email guidance from phil andrew on 01may23, the site was informed that this did not fit the definition of a protocol deviation. however, on 17jan24, the site was made aware by scharp that this is now a deviation per guidance from the protocol team and therefore is now submitting this protocol deviation.	after this event occurred, the site explored options with the local testing lab about how to proceed with participants with difficult venous access. the site was told to write ˆdifficult stick˜ on lab requisition forms so the lab is more careful with utilizing the collected blood.
Lab Assessment Deviation	Washington DC − Washington Circle	HIV−	801950495	participant presented for week 26 visit on 23aug23. due to the mobile unit being out of commission, the site was only able to complete non−clinical procedures. staff offered transport services to the crs clinic to complete the clinical procedures on the same day, but the participant refused. a split visit was planned in order to complete the remaining clinical procedures, but the participant was unable to return before the visit window closed. as a result, blood and urine were not collected for primary−endpoint assessments at week 26.	staff made numerous unsuccessful attempts to locate and re−establish contact with the participant.	the mobile unit is now back in the field and staff will continue to make every attempt to complete all visit procedures on the same day. study staff will continue to attempt to re−establish contact with the participant to return for their week 52 visit.
Lab Assessment Deviation	Washington DC − Washington Circle	HIV−	801956516	the site attempted to collect a urine sample at the participant's week 52 visit, however the participant was unable to provide a urine sample.	the site made multiple attempts to have the participant return for urine sample collection, however he did not show up. we are reporting this now as a protocol deviation per scharp guidance.	n/a (site no longer has participants in study follow−up).
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853108822	pregnancy test not performed at week 26 visit due to no male partners.	pregnancy test will be done on all female participants with reproductive potential on week 26 and week 52.	pregnancy test will be done on all female participants with reproductive potential on week 26 and week 52.
Informed Consent Process Deviation	Houston AIDS Research Team CRS	HIV−	853163608	the pid used a fake id with an alias on the screening visit, and singed the icf. the participant explained that he was concerned about his personal information "getting leaked," so he used an alias and a fake id on may 1, 2023, for the protocol screening visit.	the participant completed an attestation explaining the existence of the alias id. he signed the last approved protocol icf with texas state−issued id information.	verify the hptn 094 participant's identity during each visit .we review any government−issued id. .we ask if they have ever been to any of the public hospitals in our area. we can check the picture id filed in their medical records. . we verify that the electronic medical records' patient demographic and locator information is accurate and current. . we complete a research participant locator form as part of the screening visit records. the participant updates this document during each visit

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Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853174187	per labcorp report, urine for fentanyl was not performed due to insufficient samples. the site cannot re−contact the participant as she was placed in an emergency shelter for women in an undisclosed location.	n/a	the site has ensure that sufficient sample are sent to the local labcorp when filling up the cups.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853177331	hepatitis c antibody test was not done at week 52 visit	participant have declined to be brought back due to distance, and conflicting schedule. unable to complete hep c testing.	a schedule of events table along with printed reminders of labs necessary at each visit have been placed on the mobile unit to avoid this situation in the future.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853195711	prp test not taken at enrollment visit	prp test was taken at the next visit.	enumerate all tubes needed for collection at the visit beforehand.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853243163	unable to collected serum for specimen collection due to poor vein access.	the participant was requested to return to finish labs on a split visit but was unable to. he was requested to hydrate prior the visit, as well as using hot compresses.	request participants to hydrate prior the visit, as well as using hot compresses.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853243163	plasma sample quantity for storage is insufficient for processing.	unable to collect more sample as participant refused more attempts.	participant informed about coming back prior week 52 visit window ends for blood collection, but participant declines as he will be traveling out of city.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853247974	the lab samples were not processed by labcorp because the sst tubes were stored improperly.	the participant was contacted and informed of the issue, but he refused to come back to the mobile unit for a re−test.	how and where the storage containers for transportation have been changed, as well as their placement after use.
Conduct Of Non−Protocol Procedure	Houston AIDS Research Team CRS	HIV−	853258363	navigation sessions occurred one day after the week 26 visit	information reinforcement of when navigation sessions can happen has been given to all peer navigator coaches.	information reinforcement of when navigation sessions can happen has been given to all peer navigator coaches.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853302407	participant tested positive for hep c antibody on the week 52 visits, but did not came back for the hepatitis c rna test.	the participant was unable to be brought back to complete the blood draw.	we have spoken with the participants about the importance of the hep c rna test. we request them to keep in contact with the study in case the participant needs further test.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853309348	participant tested positive for hep c but did not come back for rna quantitative result	the participant does not have a phone or domicile, but all outreach personnel has been instructed to re−connect the participant and notify him that he has one test pending.	the participants are informed that more tests will follow if any hepatitis test turns positive, and it is essential to be available.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853362961	hepatitis c antibody test was not done at week 52 visit	participant was contacted but did not schedule a date for blood draw. participant was terminated so will not be brought back.	a schedule of events table along with printed reminders of labs necessary at each visit have been placed on the mobile unit to avoid this situation in the future.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853377894	after multiple attempts to collect samples, the participant declined any further efforts.	the participant has been invited back to complete week 52 visits labs prior visit window closure.	the participants will be instructed to hydrate prior to the visit to ease the blood drawing attempts.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853454858	gc/ct urine inadvertently not processed by lab	n/a	n/a
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853454858	missing storage location of dbs sample	the dbs sample will be collected at the next scheduled visit	the laboratory has taken measures for location and storing of samples.

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Conduct Of Non−Protocol Procedure	Houston AIDS Research Team CRS	HIV−	853454858	pn coach conducted a navigation session 3 days after the week 26 visit.	information reinforcement of when navigation sessions can happen has been given to all peer navigator coaches.	information reinforcement of when navigation sessions can happen has been given to all peer navigator coaches.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853457472	insufficient blood sample for lab based hiv, syphilis testing, hbsag, hbsab, hematology labs, plasma storage, dbs, serum. due to sclerotic vein/ hard stick	used different hard stick techniques (like hydration, warm up, bp cuff use, etc.)	we´ll use different hard stick techniques again. (like hydration, warm up, bp cuff use, etc.)
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853457472	hepatitis c antibody test was not done at week 52 visit	participant did not confirm any date to complete their week 52 visit.	a schedule of events table along with printed reminders of labs necessary at each visit have been placed on the mobile unit to avoid this situation in the future.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853460544	the participant refused to give a urine sample at week 52 visit since he "can only urinate twice a day, did not want to drink more water or wait until he felt he can urinate"	the participant is informed that he has 30 days for the visit window to close.	the crs will maintain contact with participant to collect urine sample
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853481421	plasma and dbs not collected at enrollment visit.	hydration, heat pads before venipuncture	hydration, heat pads before venipuncture
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV+	853535078	unable to collect plasma for storage due to difficult venipuncture.	the participant declined further attempts to collect sample.	participant will be advise to hydrate prior any research visit
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV+	853556415	dbs collected, but it should not have been collected for participants who are living with hiv.	dbs sample will not be taken at the next scheduled visit	a note has been added for all participants who are hiv positive in the laboratory requisition note for clarification of when a participant is hiv positive and no dbs is needed
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV+	853556415	dbs collected, but it should not have been collected for participants who are living with hiv.	laboratory requisition form will have added information to warn lab staff that dbs is not required.	a note has been added for all participants who are hiv positive in the laboratory requisition note for clarification of when a participant is hiv positive and no dbs is needed
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853589609	serum was not collected, vein collapsed and patient refused to repeat a draw.	hydration, heat pads, and bp cuff before venipuncture	hydration, heat pads, and bp cuff before venipuncture
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853589609	the pregnancy test was not performed on the week 52 visit.	the pregnancy in urine test will be done on all participants regardless of contraception used.	the pregnancy in urine test will be done on all participants regardless of contraception used.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853597111	participant tested positive for hep c but did not come back for rna quantitative result.	the hcv rna sample will be taken in the next available visit	the participant will be asked before the blood drawing process if they will accept drawing an extra sst tube in case the hcv ab test is positive.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV+	853703356	hcg test not done at the enrollment visit	the hcg test will be done regardless of the menstrual cycle of the participant.	the hcg test will be done regardless of the menstrual cycle of the participant

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Type of Deviation	Site Name	HIV Cohort	Subject ID	Description of Deviation	Plans and/or Action Taken to Address the Deviation	Plans and/or Action Taken to Prevent Future Occurrences of the Deviation
Informed Consent Process Deviation	Houston AIDS Research Team CRS	HIV−	853709959	the formatting of the informed consent form (icf) version in ucla redcap differs from the advarra−approved icf. furthermore, daids requested that all electronic systems used by clinical research sites to be approved by 12/01/2021. despite our best efforts to have the system approved, we were not able to do so due to validation issues.	we have discontinued the use of a redcap administered icf in lieu of a paper−based copy of the advarra−approved icf. consent will be obtained as a hardcopy document to be filed at vsc per protocol. a copy must be made available to the participant. all enrolled participants will be re−consented using a hardcopy icf.	we have amended the applicable icf ssp to specify the use of hardcopy icfs. the amended ssp was reviewed by each staff member and training to administer the icf as a hardcopy was provided; study site staff will be re−trained on the daids source documentation requirements and gcp guidelines. we will no longer use any electronic systems that have not been formally approved by daids prior to their launch.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853709959	gc/ct vaginal swab specimen as well as urine gc/ct specimen were collected 26−week visit.	clinician reviewed protocol and ssp with pi. future visit 3.0 and visit 4.0 will not collect preferred vaginal swab for testing gc/ct or less preferred urine specimen if participant declines the former.	future enrollment, 26−week and 52−week visits for female participants will perform one of the two tests for gc/ct, not both. future 26−week and 52−week visits will not have fentanyl urine testing performed. on 10/5/2022, staff re−training was administered by pi on details of ssp 11: laboratory and specimen management procedures with primary field clinician, medical assistants, study peer health navigators, field supervisor, and administrative assistant.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853730341	hepatitis c antibody test was not done at week 52 visit	participant has terminated so will not be brought back.	a schedule of events table along with printed reminders of labs necessary at each visit have been placed on the mobile unit to avoid this situation in the future.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853752386	insufficient blood sample for plasma, dbs and serum.	use different hard stick techniques (like hydration, warm up, bp cuff use, etc.)	we´ll use different hard stick techniques again. (like hydration, warm up, bp cuff use, etc.)
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853752386	hepatitis c antibody test was not done at week 52 visit	participant did not confirm any date to complete their week 52 visit.	a schedule of events table along with printed reminders of labs necessary at each visit have been placed on the mobile unit to avoid this situation in the future.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853811852	at enrollment, the participant denied a previous history of hepatitis, after the enrollment window visit participant never came back for hep c rna testing.	the participants have been informed about the importance of staying in contact with the research team in case further lab tests are needed. the hcv rna test will be taken in the next scheduled visit of the study.	the participants will be asked before blood sample collection if they would agree to have an extra sst tube collected in case an hcv rna sample is required if the hcv ab test is positive.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853861262	unable to collect plasma storage and dbs due to difficult venipuncture. the participant refused further attempts	the participant refused anymore blood draws after second attempt.	the participants will be asses to hydrate and blood collection staff will attempt multiple techniques for blood draw.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853865849	at enrollment, the participant denied a previous history of hepatitis, after the enrollment window visit participant never came back for hep c rna testing.	the participants have been informed about the importance of staying in contact with the research team in case further lab tests are needed. the hcv rna test will be taken in the next scheduled visit of the study.	the participants will be asked before blood sample collection if they would agree to have an extra sst tube collected in case an hcv rna sample is required if the hcv ab test is positive.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853865849	the hcg test was not done at the moment of enrollment.	the pregnancy test will be done regardless of previous sexual history and orientation.	the hcg test will be done at the next available research study visit.
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853888782	not enough blood collected at screening for plasma storage	ask participant to hydrate and use heat packs before venipuncture	ask participant to hydrate and use heat packs before venipuncture

Source: SCHARP (Carolyn) − /trials/hptn/p094/analysis/atlas/code/open/l_deviation.sas, SAS Version 9.4 (15SEP2025,7:35)

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Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853888782	plasma and dbs not collected at enrollment visit.	use heat pads, hydration and sphygmomanometer	use heat pads, hydration and sphygmomanometer
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853888782	the participant denied previous history of hepatitis. hep c rna test was not taken within the allowable window due to the inability to locate the participant.	the hcv rna test will be taken at the next scheduled visit scheduled visit	the participants will be asked prior blood drawing collection if they accept an extra sst tube for the hcv rna test in case the hcv ab test is positive
Lab Assessment Deviation	Houston AIDS Research Team CRS	HIV−	853976915	pregnancy test not done at week 26.	participant reported no pregnancies after this visit.	pregnancy test will de done regardless of menstrual cycle.
Lab Assessment Deviation	Philadelphia	HIV−	863107523	blood draw was unable to be completed for the week 26 visit due to poor venous access.	site made attempts to bring the participant back in to complete the blood draw but were unsuccessful.	site will continue retention efforts for the week 52 visit and will encourage hydration prior to the visit.
Lab Assessment Deviation	Philadelphia	HIV−	863107523	blood draw was unable to be completed for the participant´s week 52 visit due to poor venous access.	the week 52 allowable visit window now has an end date so participant has been terminated. site staff were unable to bring participant back in to complete the blood collection.	site staff to continue retention efforts.
Lab Assessment Deviation	Philadelphia	HIV−	863114801	blood draw was unable to be performed at week 52 visit due to poor venous access.	participant was unable to return for split visit to provide blood specimens prior to 30 days passing from initial week 52 visit.	site continues retention efforts.
Lab Assessment Deviation	Philadelphia	HIV−	863159634	participant was unable to provide blood specimens at week 26 visit.	attempts to bring participant back in to complete the blood draw were unsuccessful.	site staff will continue retention efforts in order to complete week 52 visit.
Lab Assessment Deviation	Philadelphia	HIV−	863159634	participant was unable to provide blood specimens due to poor venous access at week 52 visit.	participant was unable to return for a re−attempt at the blood draw prior to 30 days passing from initial week 52 visit.	site will continue encouraging all participants to be well hydrated prior to visits.
Lab Assessment Deviation	Philadelphia	HIV−	863163588	rpr testing and serum storage were unable to be completed for the week 26 visit due to poor venous access.	due to the participant living further away now, staff were unable to get them to return for another attempt at the blood draw.	site staff will continue encouraging hydration prior to visits.
Lab Assessment Deviation	Philadelphia	HIV−	863163588	due to a short draw at the week 52 visit, no blood specimens for storage were able to be obtained and rpr testing was unable to be completed.	study team unable to bring the participant back in for a re−draw within an appropriate amount of time.	study team will continue encouraging participants to hydrate well prior to visits.
Lab Assessment Deviation	Philadelphia	HIV−	863167507	blood received at quest was clotted so hemoglobin testing was not able to be performed. attempts to bring participant back in for a repeat blood draw before the 30 day screening window closed were unsuccessful.	site will continue attempting to bring participant in to complete the hemoglobin testing.	site and processing lab will have closer communication so delivery of specimen samples are more timely.
Lab Assessment Deviation	Philadelphia	HIV−	863167507	at the enrollment visit, urine for storage was erroneously not collected before randomization.	clinic staff will bring participant back in to collect the urine specimen.	reinforced to staff the need to collect all required specimens before randomization.
Informed Consent Process Deviation	Philadelphia	HIV−	863195237	participant was not consented with most recent version of the icf.	participant will be reconsented with the most recent consent form.	staff retrained on identifying correct version of consent form.
Lab Assessment Deviation	Philadelphia	HIV−	863195727	pregnancy testing was not completed at week 26 visit.	none.	progress notes updated to indicate that pregnancy testing is required at follow−up visits.

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Lab Assessment Deviation	Philadelphia	HIV−	863231318	pregnancy testing was not completed at week 26 visit.	none.	progress notes updated to indicate that pregnancy testing is required at follow−up visits.
Lab Assessment Deviation	Philadelphia	HIV−	863231318	pregnancy testing was not completed at week 52 visit.	participant has already been terminated from study.	progress notes updated to indicate that pregnancy testing is required at follow−up visits.
Lab Assessment Deviation	Philadelphia	HIV−	863294425	split visit was needed to complete enrollment procedures, however, hiv rapid testing and eligibility recheck were not performed on the second date of enrollment.	reported deviation to study team. the participant is confirmed to be hiv negative and meets eligibility criteria for enrollment.	improving workflow to avoid miscommunications in the future.
Lab Assessment Deviation	Philadelphia	HIV−	863294425	blood draw was unable to be performed for the week 26 visit due to poor venous access.	site made attempts to bring the participant back in to complete the blood draw but were unsuccessful.	site will continue retention efforts for the week 52 visit.
Lab Assessment Deviation	Philadelphia	HIV+	863304060	local laboratory erroneously did not perform sti testing on oral swab collected on 8/25/2021 (date of randomization).	site received encouragement on 8/26/2021 site call that enrollment procedures might be able to be completed regardless of window so site re−collected oral swab on 9/30/2021. however, later guidance released on 10/14/2021 restricted enrollment procedures to be completed within 30 days of screening.	this deviation was not noted until after participant had already discontinued from the study.
Lab Assessment Deviation	Philadelphia	HIV−	863312660	due to poor venous access, the blood draw was short and serum was not able to be stored at the week 52 visit.	attempts at bringing the participant back in for a repeat blood draw were unsuccessful.	participant has now completed the study.
Lab Assessment Deviation	Philadelphia	HIV−	863325352	blood draw was unable to be completed for the participant´s week 26 visit due to poor venous access.	site staff were unable to bring participant back in to complete the blood collection prior to the visit window closing.	site staff continued retention efforts and participant completed their week 52 visit.
Lab Assessment Deviation	Philadelphia	HIV−	863329139	serum storage was unable to be completed for the week 52 visit.	the participant was unable to provide any blood specimens on 4/9 due to poor venous access. they returned for another attempt on 4/16, but was unable to provide the full amount of blood needed to complete all storage and testing requirements.	staff to continue encouraging hydration prior to visits.
Lab Assessment Deviation	Philadelphia	HIV−	863374192	serum, plasma, and dbs storage were not completed for the week 52 visit due to a short draw.	participant was scheduled to come back for a repeat blood draw on 4/29/2024 but did not come in. since 30 days have now passed since the initial week 52 visit, efforts to collect these specimens have been halted.	site staff will continue encouraging participants to hydrate prior to visits.
Lab Assessment Deviation	Philadelphia	HIV−	863384178	blood draw was unable to be completed for the participant´s week 52 visit.	clinic staff attempted to bring participant back in to complete these procedures but were unsuccessful.	site will continue retention efforts.
Informed Consent Process Deviation	Philadelphia		863385984	participant was not consented with most recent version of the icf.	participant will be reconsented with the most recent consent form.	staff retrained on identifying correct version of consent form.
Lab Assessment Deviation	Philadelphia	HIV−	863411717	blood draw was unable to be performed for the week 26 visit due to poor venous access.	site made attempts to bring the participant back in to complete the blood draw but were unsuccessful.	site will continue retention efforts for the week 52 visit.

Source: SCHARP (Carolyn) − /trials/hptn/p094/analysis/atlas/code/open/l_deviation.sas, SAS Version 9.4 (15SEP2025,7:35)

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Lab Assessment Deviation	Philadelphia	HIV−	863412814	blood draw was unable to be performed at week 26 visit due to poor venous access.	participant did not return for split visit to provide blood specimens prior to 30 days passing from initial week 26 visit.	staff will continue retention efforts and encourage hydration.
Lab Assessment Deviation	Philadelphia	HIV−	863445116	due to a short draw at the week 52 visit, no serum was able to be stored.	attempts at bringing the participant back in for a repeat blood draw were unsuccessful.	the participant has not completed the study.
Lab Assessment Deviation	Philadelphia	HIV+	863458792	pregnancy testing was not completed at week 26 visit.	none.	progress notes updated to indicate that pregnancy testing is required at follow−up visits.
Informed Consent Process Deviation	Philadelphia	HIV−	863480659	participant was not consented with most recent version of the icf.	participant will be reconsented with the most recent consent form.	staff retrained on identifying correct version of consent form.
Informed Consent Process Deviation	Philadelphia	HIV−	863488507	participant was not consented with most recent version of the icf.	participant will be reconsented with the most recent consent form.	staff retrained on identifying correct version of consent form.
Lab Assessment Deviation	Philadelphia	HIV−	863490092	due to poor venous access, the participant was unable to provide blood specimens for their week 26 visit.	the visit occurred one day prior to the window closing and the site was unable to attempt another blood draw in that time frame.	site staff to continue to encourage hydration prior to study visits.
Lab Assessment Deviation	Philadelphia	HIV+	863492977	blood draw was unable to be completed for week 26 assessment due to poor venous access.	participant did not return to complete blood collection.	clinic staff continued retention efforts and were able to complete all procedures for week 52 visit.
Informed Consent Process Deviation	Philadelphia	HIV−	863506166	participant was not consented with most recent version of the icf.	participant will be reconsented with the most recent consent form.	staff retrained on identifying correct version of consent form.
Failure To Follow Randomization Or Blinding Procedures	Philadelphia	HIV−	863506166	acasi survey completed before randomization occurred.	documented correct timing of events.	staff re−educated on only conducting enrollment procedures after randomization.
Informed Consent Process Deviation	Philadelphia	HIV−	863512259	participant was not consented with most recent version of the icf.	participant will be reconsented with the most recent consent form.	staff retrained on identifying correct version of consent form.
Lab Assessment Deviation	Philadelphia	HIV−	863517433	blood draw was unable to be completed for week 52 assessment due to visit being completed at an offsite location.	participant was unable to return to the mobile unit to complete the blood collection within the 30−day allowable window to complete a split visit.	site staff will continue making every effort to complete all required procedures at each visit.
Lab Assessment Deviation	Philadelphia	HIV−	863527450	no specimens were collected for the week 26 visit due to visit occurring remotely.	protocol team gave permission to conduct visit remotely.	site will reassess for the week 52 visit whether the participant has returned or is willing to return to philadelphia to conduct an in−person visit.
Lab Assessment Deviation	Philadelphia	HIV−	863527450	due to poor venous access, the blood draw was short at the week 52 visit and no serum was able to be stored.	clinic was unable to bring the participant back in for a repeat blood draw to complete serum storage.	clinic will continue encouraging participants to hydrate well prior to visits.
Lab Assessment Deviation	Philadelphia	HIV−	863548162	no specimens were collected for week 52 visit.	the participant was not able to leave treatment center for in−person visit so the visit was conducted remotely.	no further action taken.
Lab Assessment Deviation	Philadelphia	HIV−	863592967	hiv rapid test at enrollment performed after randomization	hiv rapid test completed	retraining of staff
Informed Consent Process Deviation	Philadelphia	HIV−	863611834	participant was not consented with most recent version of the icf.	participant will be reconsented with the most recent consent form.	staff retrained on identifying correct version of consent form.

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Lab Assessment Deviation	Philadelphia	HIV−	863611834	baseline values were not obtained for participant due to inability to draw blood at enrollment.	discussed situation with protocol team at time of event.	discussions with protocol team led to protocol amendment which changed randomization to end of enrollment instead at beginning. this has removed the possibility of enrolling a participant without a blood draw.
Unreported Sae	Philadelphia	HIV−	863611834	sae was not reported within 72 hours of site notification of event.	sae reported in database.	staff re−educated on timeline of sae reporting.
Breach Of Confidentiality	Philadelphia	HIV−	863611834	phi erroneously sent to the study team	notification sent to the cmc to delete email with phi	records will be redacted thoroughly prior to sending
Lab Assessment Deviation	Philadelphia	HIV−	863628395	pregnancy testing was not completed at week 26 visit.	visit window has closed.	progress notes updated to indicate that pregnancy testing is required at follow−up visits.
Lab Assessment Deviation	Philadelphia	HIV−	863634798	remote visit was conducted for the week 52 visit due to the participant being out of the city. therefore, no specimens were collected for this visit.	participant planned on returning to the city within the next few weeks and would provide specimens then, however, these plans fell through so no specimens will be collected.	participant has now completed the study.
Lab Assessment Deviation	Philadelphia	HIV−	863637074	pregnancy testing was not completed at week 26 visit.	none.	progress notes updated to indicate that pregnancy testing is required at follow−up visits.
Lab Assessment Deviation	Philadelphia	HIV−	863637089	unable to obtain any specimens for week 52 visit.	visit was held remotely as the participant is currently 4 hours outside of philadelphia and does not wish to return. site received allowance from the protocol team to conduct visit remotely.	site staff to continue retention efforts.
Lab Assessment Deviation	Philadelphia	HIV−	863642142	blood draw was unable to be performed at week 26 visit on 12/8/2023.	participant was scheduled to return for another attempt at the blood draw on 12/12/2023 but never showed up.	site will continue retention efforts and to encourage hydration prior to visits.
Lab Assessment Deviation	Philadelphia	HIV−	863642433	blood specimens were unable to be collected at v3.0 due to poor venous access.	site attempted to bring participant back in to complete the assessment but were unable to do so within the visit window.	site will continue retention efforts.
Lab Assessment Deviation	Philadelphia	HIV−	863664315	blood draw was not performed for week 26 visit due to poor venous access.	site made attempts to bring participant back in to complete the blood draw but were unable to do so.	site will continue retention efforts to complete the week 52 visits and will encourage hydration prior to the visit.
Lab Assessment Deviation	Philadelphia	HIV+	863672963	blood draw was unable to be performed for the week 26 visit due to dehydration and poor venous access.	site made attempts to bring the participant back in to complete the blood draw but were unsuccessful.	site will continue retention efforts for the week 52 visit.
Lab Assessment Deviation	Philadelphia	HIV−	863679538	blood draw was unable to be performed at week 26 visit due to poor venous access.	participant was scheduled to return for the blood draw but did not show.	clinic staff will continue retention efforts and will encourage hydration prior to study visits.
Informed Consent Process Deviation	Philadelphia	HIV−	863698330	participant was not consented with most recent version of the icf.	participant will be reconsented with the most recent consent form.	staff retrained on identifying correct version of consent form.
Lab Assessment Deviation	Philadelphia	HIV−	863698330	baseline values were not obtained for participant due to inability to draw blood at enrollment.	discussed situation with protocol team at time of event.	discussions with protocol team led to protocol amendment which changed randomization to end of enrollment instead at beginning. this has removed the possibility of enrolling a participant without a blood draw.
Lab Assessment Deviation	Philadelphia	HIV−	863698330	pregnancy testing was not completed at week 26 visit.	none.	progress notes updated to indicate that pregnancy testing is required at follow−up visits.

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Lab Assessment Deviation	Philadelphia	HIV−	863698330	pregnancy testing was not completed at week 52 visit.	participant has already been terminated from study.	progress notes updated to indicate that pregnancy testing is required at follow−up visits.
Unreported Sae	Philadelphia	HIV−	863761412	saes due to hospitalization not reported within 72 hours of site notice.	saes reported.	staff re−educated on appropriate timelines for reporting saes.
Lab Assessment Deviation	Philadelphia	HIV−	863761412	pregnancy testing was not completed at week 26 visit.	not applicable.	progress notes updated to indicate that pregnancy testing is required at follow−up visits.
Lab Assessment Deviation	Philadelphia	HIV−	863761412	pregnancy testing was not completed at week 52 visit.	participant has already been terminated from study.	progress notes updated to indicate that pregnancy testing is required at follow−up visits.
Lab Assessment Deviation	Philadelphia	HIV−	863764036	due to participant being located out of state and unable to return, no specimens were able to be collected for the week 52 visit.	all procedures that were able to be performed virtually, were completed. protocol team informed.	no further action taken.
Informed Consent Process Deviation	Philadelphia	HIV−	863801021	participant was not consented with most recent version of the icf.	participant will be reconsented with the most recent consent form.	staff retrained on identifying correct version of consent form.
Lab Assessment Deviation	Philadelphia	HIV−	863801021	baseline values were not obtained for participant due to inability to draw blood at enrollment.	discussed situation with protocol team at time of event.	discussions with protocol team led to protocol amendment which changed randomization to end of enrollment instead at beginning. this has removed the possibility of enrolling a participant without a blood draw.
Breach Of Confidentiality	Philadelphia	HIV−	863801021	phi erroneously sent to the study team	notification sent to the cmc to delete email with phi	records will be redacted thoroughly prior to sending
Lab Assessment Deviation	Philadelphia	HIV−	863801021	pregnancy testing was not completed at week 25 visit.	none.	progress notes updated to indicate that pregnancy testing is required at follow−up visits.
Informed Consent Process Deviation	Philadelphia		863805248	participant was not consented with most recent version of the icf.	participant will be reconsented with the most recent consent form.	staff retrained on identifying correct version of consent form.
Informed Consent Process Deviation	Philadelphia	HIV−	863809480	participant was not consented with most recent version of the icf.	participant will be reconsented with the most recent consent form.	staff retrained on identifying correct version of consent form.
Lab Assessment Deviation	Philadelphia	HIV−	863809480	baseline values were not obtained for participant due to inability to draw blood at enrollment.	discussed situation with protocol team at time of event.	discussions with protocol team led to protocol amendment which changed randomization to end of enrollment instead at beginning. this has removed the possibility of enrolling a participant without a blood draw.
Lab Assessment Deviation	Philadelphia	HIV−	863809480	participant did not complete blood collection and pregnancy testing for their week 52 assessment.	clinic staff attempted to bring participant back in to complete these procedures but were unsuccessful.	site will continue retention efforts.
Lab Assessment Deviation	Philadelphia	HIV−	863852711	at enrollment, plasma storage was short on volume and serum storage inadvertently did not occur.	site attempted to bring participant back in to complete assessments before 30−day screening window closed but were unsuccessful.	site continues efforts to collect and store these specimens.
Lab Assessment Deviation	Philadelphia	HIV−	863852711	blood draw was unable to be completed for week 52 assessment due to poor venous access.	attempts were made to bring the participant back in to complete the blood draw but were unsuccessful.	clinic staff will continue to encourage participants to hydrate prior to study visits.

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Lab Assessment Deviation	Philadelphia	HIV+	863867613	blood draw did not occur at week 26 visit.	site attempted to bring participant back in to complete this procedure before the visit window closed but were unsuccessful.	site will continue retention efforts and will attempt to bring participant back in for week 52 visit.
Lab Assessment Deviation	Philadelphia	HIV+	863897363	enrollment procedures were started before hiv laboratory testing from the screening visit were resulted.	enrollment procedures paused until results were obtained to confirm hiv status.	reinforced hiv algorithm timeline to staff.
Lab Assessment Deviation	Philadelphia	HIV+	863897363	hiv rapid test was not completed for enrollment visit.	informed protocol team of event.	reinforced timeline of hiv algorithm to staff.
Lab Assessment Deviation	Philadelphia	HIV−	863919853	no blood drawn due to poor venous access. therefore protocol required testing and storage were not able to be performed.	participant was unable to be brought back to the mobile unit to collect blood prior to the closing of the 30−day visit window for week 52.	staff continue study retention efforts and make all efforts to obtain the required specimens for each visit.
Informed Consent Process Deviation	Philadelphia		863939602	participant was not consented with most recent version of the icf.	participant will be reconsented with the most recent consent form.	staff retrained on identifying correct version of consent form.
Lab Assessment Deviation	Philadelphia	HIV−	863949633	due to participant living 3 hours away from philadelphia and not being able to return for an in−person visit, no specimens were able to be collected for the week 52 visit.	all procedures that were able to be performed virtually, were completed. permission obtained from protocol team.	no further action taken.
Lab Assessment Deviation	Philadelphia	HIV+	863966687	no blood was obtained for the week 52 visit due to poor venous access.	the participant did not return for a split visit to attempt a re−draw prior to 30 days passing from the initial week 52 visit.	this was the final study visit for this participant.

Source: SCHARP (Carolyn) − /trials/hptn/p094/analysis/atlas/code/open/l_deviation.sas, SAS Version 9.4 (15SEP2025,7:35)