Annotated Study Book for Study Design: AWARE_RATER

Study Design Version: 1.0

AWARE RATER

Generated by Central Designer TM

May 11, 2010 2:58PM

	Element		Sys	stem			
	Assessment	CRF	Screening (Scr) [S]	Enrollment (Enr) [S]	CI (CI) [S]	ARM1 (ARM1) [U]	ARM2 (ARM2) [U]
	Visit Start Hours		0	0	0	1	2
1	SCREENING	SCR	1				
2	ENROLLMENT	ENR		1			
3	Counselor Information	CI			1		
4	ARM 1-PRE-RESULTS SESSION	PRS1				1-RF	
5	ARM 1-FINGERSTICK RAPID RESULTS SESSION-NEGATIVE RESULTS	FRRN1				2-RF	
6	ARM 1-FINGERSTICK RAPID RESULTS SESSION-INVALID RESULTS	FRRI1				3-RF	
7	ARM 1-FINGERSTICK RAPID RESULTS SESSION-REACTIVE RESULTS	FRRR1				4-RF	
8	ARM 2-FINGERSTICK RAPID PRE-RESULTS SESSION	FRPR2					1-RF
9	ARM 2-FINGERSTICK RAPID RESULTS SESSION-NEGATIVE RESULTS	FRRN2					2-RF
10	ARM 2-FINGERSTICK RAPID RESULTS SESSION-INVALID RESULTS	FRRI2	1				3-RF
11	ARM 2-FINGERSTICK RAPID RESULTS SESSION-REACTIVE RESULTS	FRSR2					4-RF

A٧	AWARE_RATER: SCREENING (SCR) [frSCR]								
Scr	Screening [stSCRN]								
1. [*] ✔	Subject Initials [read-only] [Initials]	[SUBINIT] A3							
2. [*] ✔	Counselor Number [Counselor Number]	[COUNNO] A5							
К	Key: [*] = Item is required [✓] = Source verification required								

AWARE_RATER: ENROLLMENT (ENR) [frenr]									
1.* Counselor Number	[ENRCOUN]								
✓ [Counselor Number]	A13								
Key: [*] = Item is required [✓] = Source verification required									

AV	AWARE_RATER: Counselor Information (CI) [frCI]									
. [s	. [stCl]									
	WARNING: ANY CHANGES TO THESE FIELDS BELOW WILL CHANGE THE IDENTIFICATION OF THIS SUBJECT - Changes that make these fields empty will not be acted upon and the prior values will remain for the purpose of identification.									
	L* Counselor Number [ENRCOUN] [Counselor Number] A13									
Ke	Key: [*] = Item is required [✓] = Source verification required									

# F	Participant ID#:	Session Rev Date: Da	view Sessio ate: Lengtl		Provide an introduction:	Frame HIV conseling session	Provide general testing information	Provide HIV rapid test	Enhance participant perception risk		Identify client's ambivalence risk behavior	Examin previous risk reduction	readiness		I dentify sources of support for participant's risk reduction plan	Rapid HIV testing conducted
1	100013															
. [S	Participan	t ID#:							[PR	S1PTID]						
✓	[Participa								N4							
2.* ✔		Session Date: [Session Date:]						1.0	S1STDT] ▼ / Req ▼ / Re	eq 💟 (2010-2012)						
3.* ✔	Review D									S1EDT] ▼ / Req ▼ / Re	eq 🛃 (2010-2012)					
4.* ✓		Session Length: [Session Length]						[PR N3	s1MM] mins							
5.* ✓		Reviewer #: [Reviewer #:]						[PR N4	S1REV]							
То	what exter	nt did the co	unselor: [s	PRS12]												
6.* ✔	Introduce about aud	1. Provide an introduction: Introduce self, inquire about visit experience thus far, provide segue to session focus, remind participant about audio recording, mention possibility of counselor jotting down a few notes. [Provide an introduction:]						17	[PRS101] [RateScale]							
7.* ✓	Share info STDs; cre	2. Frame HIV counseling session: Share information about rapid HIV test; provide HIV test; discuss possible risk behaviors for HIV and othe STDs; create a risk reduction plan; provide information about the HIV test and test results. [Frame HIV conseling session]						1.0	[PRS102] [RateScale]							
8.* ✓	Type and results; fu	urther question	possible resu	ults of test, r esting.	need for immedia	ate additiona	al testing if for	invalid or	17	Ve [PRS110] [RateScale]						
9.* ✓	Provide te testing re counseling	 [Provide general testing information] 4. Provide HIV rapid test: Provide testing: review consent process, have participant sign and date consent; counselor sign consent. testing rejected, probe for reasons; strategize ways to overcome obstacles; continue with risk reduction counseling. [Provide HIV rapid test] 						sent. If	[PRS111] [RateScale]							
10. ✓	Feelings a transmitte behavior.	5. Enhance participant's perception of risk: Feelings around discussing personal subject matter; assess participant's understanding of how HIV is transmitted; assess participant's understanding of STD transmission; discuss participant's general risk					s [Ra	[PRS103] [RateScale]								
11. 🗸	Explore an other fact around st	6. Assess for risk and contributing factors: Explore ambivalence: Explore recent risky episodes (with emphasis on unprotected vaginal and anal sex); other factors contributing to risk such as substance use and partner aspects; communication with partners around status, testing; identify participant's ambivalence around risk behavior. [Assess for risk and contributing factors:]					sex); [Ra	[PRS104] [RateScale]								
12. ✓	Client's fe and accep	 Identify client's ambivalence re: risk behavior: Client's feelings around risk behavior; acceptable; unacceptable behaviors; change over time of behavior and acceptable limits, impact of testing on behavior. [Identify client's ambivalence risk behavior] 					1.0	[PRS105] [RateScale]								
13. ✔	Previous s people th	Rentity client's ambivalence risk benavior] 8. Examine pervious risk reduction strategies: Previous successful, unsuccessful strategies; biggest factors contributing to risk (particular situations, people that make safer sex more difficult). [Examin previous risk reduction]							[PRS106] [RateScale]							

14. [*] ✔	9. Summarize risk, factors, readiness for change: Key issues and factors contributing to risk; participant's input; participant's level/readiness (ambivalence around risk behavior) to make change; convey concern about participant's risk. [summarize risk, factors, readiness for change:]	[PRS107] [RateScale]
15. [*] ✔	10. Negotiate risk reduction plan: Explore possible realistic steps (try to address unprotected vaginal and anal sex); map out the concrete steps (who, what, where, and how); problem solve potential roadblocks to plan; provide role-play; write plan on paper. [Negotiate risk reduction plan]	[PRS108] [RateScale]
16.* ✔	 Identify sources of support for participant's risk reduction plan: Get participant to identify someone specific for support; brainstorm when and how to enlist support from person; convery confidence in client's ability to carry out plan. [Identify sources of support for participant's risk reduction plan] 	[PRS109] [RateScale]
17.* ✓	12. Was Rapid HIV testing conducted? [Rapid HIV testing conducted]	[PRS112] [N:0] [PRS112a] No [N:1] Participant did not accept rapid HIV testing [N:2] Participant did not sign HIV Informed Consent for rapid HIV testing [N:3] Participant did not return for results session [N:1] Yes
Key	r: [*] = Item is required [✓] = Source verification required	·

Codelist Values and Tables: ARM 1-PRE-RESULTS SESSION										
Codelist RefName	Codelist Data Type	Label	Code	Codelist I tem RefName	Data Variable RefName					
RateScale	Integer	Not At All	0	ciNTATALL	PRS101, PRS102,					
		Somewhat	1	ciSomewhat	PRS110, PRS111,					
		Mostly	2	ciMostly	PRS103, PRS104, PRS105.					
		Completely	3	ciCompletely	PRS105, PRS106, PRS107,					
		Not Rated	95	CINTRATED	PRS108, PRS109					

AV	VARE_RA	WARE_RATER: ARM 1-FINGERSTICK RAPID RESULTS SESSION-NEGATIVE RESULTS (FRRN1) - Repeating Form [frFRRN1]											
#	Participant ID#:	Session Date:	Review Date:	Session Length	Reviewer #:	Immediately provide test results:	Explore reaction to negative test result:	Remind participant of window period of test:	Revisit risk reduction plan	Address tough-to- manage issues:	Provide condom demonstration:	Close session:	
' [s	tFRRN11]												
1.* ✓	Participant [Participant							[FRRN1PID] N4					
2.* ✔	Session Dat [Session Da							[FRRN1SDT] Req 💽 / Req 💽 / Req 💽 (20	010-2012)				
3.* ✔	Review Date [Review Date							[FRRN1EDT] Req ♥ / Req ♥ / Req ♥ (20	010-2012)				
4.* ✔	Session Length: [Session Length]							[FRRN1MM] N3 mins					
5.* ✔	Reviewer # [Reviewer #							[FRRN1REV] N4					
То	what extent	did the cou	unselor: [s	tFRRN12]									
5.* ✓	1. Immedia Test result i [Immediate		ive (negativ	/e).				[FRRN101] [RateScale]					
7.* ✓	2. Explore r Feeling, tho [Explore rea		nd negative	test result.				[FRRN102] [RateScale]					
3.* ✓	Takes 2 we	eks to 6 mo esting shou	nths for HIN Id occur at	3 months fro		najority of people develop nt exposure; need to pro		[FRRN103] [RateScale]					
9.* ✔		sible impact /s participan	of negative t can receiv	e test results ve support fo		exual/substance use beha others.	vior; support plan;	[FRRN104] [RateScale]					
10. ✓	Thoughts al assistance.	5. Address tough-to-manage issues: Thoughts about professional support (clinic staff or others) for specific issues; sources for professional						[FRRN105] [RateScale]					
11. ✓	 6. Provide condom demonstration: If accepted, demonstrate proper condom usage; have participant direct counselor by reading out loud the handout or vice versa; inquire of any questions; provide condoms and lubricant. [Provide condom demonstration:] 						reading out loud the	[FRRN106] [RateScale]					
12. ✓	* 7. Close session: Inquire of any last questions; inquire/discuss other remaining study activities (STD specimen collection, clinician visit, exit interview); thank participant for study participation; ensure next appointment (6 month) is scheduled; remind participant of payment for contacting staff to verify locating information. [Close session:]						ippointment (6 month)	[FRRN107] [RateScale]					
Ke	ey: [*] = Item	is required [✓] = Source	e verification r	equired								

Codelist Values and Tables: ARM 1-FINGERSTICK RAPID RESULTS SESSION-NEGATIVE RESULTS

Codelist RefName	Codelist Data Type	Label	Code	Codelist I tem RefName	Data Variable RefName
RateScale	Integer	Not At All	0	ciNTATALL	FRRN101,
		Somewhat	1	ciSomewhat	FRRN102, FRRN103.
		Mostly	2	ciMostly	FRRN104,
					FRRN105,

Completely
ompletely

# I	Participant ID#:	Session Date:	Review Date:	Session Length	Reviewer #:	Immediately provide test result and meaning of result:	Explore reaction to invalid test result:	Remind participant of need for immediate retesting:	Examine testing process and readiness to be retested:		
[et	FRRI1]										
.*	Participant ID [Participant II						[FRRI 1PID] N4				
	Session Date: [Session Date	:]					[FRRI 1SDT] Req 👽 / Req 👽 / Req 👽 (2010-2012)				
	Review Date: [Review Date:]					[FRRI 1EDT] Req ♥ / Req ♥ / Req ♥ (2010-2012)			
4.* ✓	Session Lengt [Session Leng						[FRRI 1MM] N3 mins				
	Reviewer #: [Reviewer #:]						[FRRI 1REV] N4				
To v	vhat extent c	lid the coun	selor: [stFF	RI 12]							
✓	Test result is i sample proces	nvalid; mear sing.	ns we do not	meaning of re know the resu neaning of res	ult; could be p	problem with: test kit, sample collection,	[FRRI 101] [RateScale]				
~	2. Explore rea Apologize for retested. [Explore react	unfortunate e	experience; e	examine feelin	gs, thoughts	about invalid test result and need to be	[FRRI 102] [RateScale]				
✓	Need to collec	t another fin	gerstick rapi	ediate retesting d sample imm iate retesting:	ediately; resu	Its will be ready in 20 minutes.	[FRRI 103] [RateScale]				
•	 * 4. Examine testing process and readiness to be retested; retest: Explain the retesting process; inquire if any further questions, comments before retesting; explore waiting for results (again) and strategize coping plan during wait period: proceed with retesting; IF refusing further testing: strategize some testing: oral confirmatory or schedule testing appointment. [Examine testing process and readiness to be retested:] 										
	/: [*] = Item is		1 6		1		1				

Codelist Values and Tables: ARM 1-FINGERSTICK RAPID RESULTS SESSION-INVALID RESULTS

Codelist RefName	Codelist Data Type	Label	Code	Codelist I tem RefName	Data Variable RefName			
RateScale	Integer	Not At All	0	ciNTATALL	FRRI101,			
		Somewhat	1	ciSomewhat	FRRI102, FRRI103,			
		Mostly	2	ciMostly	FRRI104			
		Completely	3	ciCompletely				
		Not Rated	95	ciNTRATED				

≠ Pa	articipant ID#:	Session Date:	Review Date:	Session Length	Reviewer #:	Immediately provide test result and meaning of result:		Remind participant of need for immediate retesting:	Examine readiness for further testing and conduct additional testing:	Assess coping ability/need for additional support:	Assist participant in making a plan for self care:	Arrange for counselor care call:	Broach risk reduction to self and others:	Stress importance of returning for confirmatory test result:		
「stl	FRRR11]															
 I.* ✔	Participan [Participar								[FRRR1PID]							
<u>2</u> .* ✓	Session D [Session [[FRRR1SDT] Req 👽 / Req 👽	/ Req 💽 (2010-2012	?)					
3.* ✔	Review Da [Review D								[FRRR1EDT] Req 👽 / Req 💽	/ Req 💽 (2010-2012	:)					
1.* ✔	Session Le	0							[FRRR1MM] N3 mins							
5.* ✓	Reviewer #: [Reviewer #:]								[FRRR1REV] N4							
ro w	hat exten	t did the	counselo	or: [stFRI	RR12]				· · · · · · · · · · · · · · · · · · ·							
ó.* ✓	1. Immediately provide test result and meaning of result: Test result is reactive; antibodies to HIV were detected; small chance of false positive result; additional testing is needed. [Immediately provide test result and meaning of result:]								[FRRR101] [RateScale]							
∕.* ✓	2. Explore Feelings, f [Explore r	houghts,	questions	around re	eactive test	result; reassure parti	cipant staff is a	vailable for suppo	[FRRR102]							
3. [*] ✓	Will collec for confirm	t venous b natory res	lood conf ults.	irmatory 1	diate retest est; results iate retestir	s ready in about two v	veeks; will be s	cheduled to returr	[FRRR103] [RateScale]							
9.* ✓	Inquire if strategize some test	any furthe coping pla ing: oral c	r question an during onfirmato	ns, comme wait perio ory or sche	ents before od; PROCEE edule testing	uct additional testing: further testing; explo D with TESTING. IF re g appointment. t additional testing:]										
IO.* ✔	Provide su brainstorn	ipport; ass n strategie	sess for se s to avoid	elf-harm (d self-harr		o others); and assess tance use; provide ref		use substances ar	[FRRR105] [RateScale]							
I1. [*] ✔	Make a pla call to frie	an for toda nd/family	ay, after l from offic	eaving the	or self care: office; iden self care:]	ntify person(s) who w	ould be suppor	tive; offer to make	[FRR106] [RateScale]							
I2. [*] ✔	Describe sees call, askedule call, as a constant as a set of sease to study affine during the surely IF second all								[FRRR107] [RateScale]							
I3. [*] ✔	 8. Broach risk reduction to self and others: Explain importance of reducing risk to self and others; explore possibility of putting others at risk. [Broach risk reduction to self and others:] 							[FRR108] [RateScale]								
14.								[FRRR109] [RateScale]								
Key: [*] = Item is required [✓] = Source verification required																

Codelist Values and Tables: ARM 1-FINGERSTICK RAPID RESULTS SESSION-REACTIVE RESULTS											
Codelist RefName	Codelist Data Type	Label	Code	Codelist I tem RefName	Data Variable RefName						
RateScale	Integer	Not At All	0	CINTATALL	FRRR101, FRRR102.						
		Somewhat	1	ciSomewhat	FRRR103,						
		Mostly	2	ciMostly	FRRR104, FRRR105,						
		Completely	3	ciCompletely	FRRR106, FRRR107,						
		Not Rated	95	ciNTRATED	FRRR108, FRRR109						

Image: Text Part in the second sec	AWARE_F	WARE_RATER: ARM 2-FINGERSTICK RAPID PRE-RESULTS SESSION (FRPR2) - Repeating Form [frFRPR2]													
Perturbation Perurbition Perurbition Perturbition Perturbition Pe												Provided content beyond ARM 2 script:			
Perturbation Perurbition Perurbition Perturbition Perturbition Pe	stFRPR211														
I [Session Date:] Perior V / Perior V / Perior V / Perior V / Perior V (Perior V (2010-2012) Review V at: [Review Date:] Perior V / Perior V / Perior V / Perior V (Perior V (2010-2012) Review V at: [Review V at: [Session Langth] IFSPP2201] [Review V at: [Reviewer #:] IFSPP2201] [Review V at: [Reviewer #:] V at Action Langth IFSPP2201] [Reviewer #:] IFSPP2201] [Reviewer #:] I Provide an Inroduction: Introductin: Introduction: Introduction: Introduction: I	1.* Participa														
[Review Date:] Req ♥ /	<u>c</u> .														
i Session Length) N3 mins * Reviewer #:] [FRPR2RV] (Reviewer #:] [FRPR2RV] v= V=t extent did the counselor: [stFRPR22] [FRPR201] * Revide an introduction: Introduce soft, inquire about visit experience. [Provide an introduction:] [FRPR202] • 1. Provide an introduction: Introduce soft, inquire about visit experience. [Provide an introduction:] [FRPR201] • 2. Provide general testing information: Collecting fingerstick sample: testing information: Collecting fingerstick sample: testing information] [FRPR203] • 2. Provide filt invalid or reactive: conflorith nature of testing: window period. [Provide Init radius consent process, participant sign to and date consent: counselor to sign to git in a sign to a stackes: if testing still registed, see about remaining study activities (STD Specimen collection, clinician visit, exit interview); testing information. [Provide HIV rapid test] [FRPR203] [ReteScale] ♥ * 4. Was Rapid HIV testing conducted? [Repid HIV testing conducted? [FRPR204] [No 0] [CFRPR205] [No 0] [Provide AIW rapid test] [No 1] © Participant did not accept rapid HIV testing [No 2] © Participant did not accept rapid HIV testing [ReteScale] ♥ * 5. Provided content beyond ARM 2 script: Di documeted provide AIM 1 content or other non-scripted material or counseling such as providing rafeerals for HIV testing perception or risk, coupting risk, incidents and conting rafeeras (aubstance use, etc), revid										Req 🔽 (2010-2012)					
[Review #:] M • [Review #:] M • Untraduce statent did the counselor: [stFRPR22] Freme201 • 1. Provide an introduction: Introduce static state about tisk experience. [Provide an introduction:] [FRPR201] [Referscale] • • 2. Provide general testing information: Collecting fingerstick sample: testing information] [FRPR202] [Referscale] • • 7. Provide testing: information] [FRPR203] [Referscale] • • 7. Provide testing: information information information of the contacting staff to verify locating information. [Provide testing: infacepted, review consent process, participant sign to and date consent; counselor to sign consent; if testing rejected, growe on collection, clinicant wist, exit, interview); ensure 6 monin appointment is scheduled; remind participant of payment for contacting staff to verify locating information. [Provide HV resting conducted? • [Repid HV testing conducted] [FRPR204] [N: 0] • [FRPR204] [N: 0] • Participant did not accept rapid HV testing [N: 3] • Participant did not accept rapid HV testing [N: 3] • Participant did not accept rapid HV testing [N: 3] • Participant did not accept rapid HV testing [N: 3] • Participant did not accept rapid HV testing [N: 3] • Participant did not accept rapid HV testing [N: 3] • Participant did not accept rapid HV testing [N: 3] • Participant did not accept rapid HV testing [N: 3] • Participant did not accept															
 1. Provide an introduction: Introduce self, inquire about visit experience. [Provide general testing information:] 2. Provide general testing information: Collecting information] 3. Provide general testing information] 4. Was Rapid HIV rapid test: Provide testing: if accepted, review consent process, participant sign to and date consent: counselor to sign consent; if testing rejected, see about remaining study activities (STD specimen collection, clinician visit, exit interview); ensure 6 month appointment is scheduled; remind participant of payment for contacting staff to verify locating information. [Provide HIV rapid test] 4. Was Rapid HIV testing conducted? [Rapid HIV testing conducted] 5. Provided content beyond ARM 1 content or other non-scripted material or counseling such as providing referrals for HIV testing ageneies, enhancing perception of risk, exploring risk incidents and content and pattern, negotiating a risk reduction plan, identifying sources of support, motivating participant to get restord, or other information plan, identifying sources of support, motivating participant to get restord, or other information plan, identifying sources of support, motivating participant to get restord, or other information plan, identifying sources of support, motivating participant to get restord, or other information plan, identifying sources of support, motivating participant to get restord, or other information plan to ARM 2 script:] [Provided content beyond ARM 2 script:] [Provided content beyond ARM 2 script:] 															
 introduce self, inquire about visit experience. [Provide an introduction:] Introduction:] Introduction	To what exte	nt did the cou	unselo	or: [stFRPR2	22]										
 Collecting fingerstick sample: testing time: meaning of negative, invalid, reactive result; need to retest immediately if invalid or reactive: confidential nature of testing; window period. (Provide general testing information) Provide HIV rapid test: Provide testing: if accepted, review consent process, participant sign to and date consent; counselor to sign consent; if testing rejected, probe for reasons; strategize ways to overcome obstacles; if testing still rejected, see about remaining study activities (STD specimen collection, clinician visit, exit interview); ensure 6 month appointment is scheduled; remind participant of payment for contacting staff to verify locating information. (Provide HIV rapid test] 4. Was Rapid HIV testing conducted? (Rapid HIV testing conducted] 5. Provided content beyond ARM 2 script: Did counselor provide ARM 1 content or other non-scripted material or counseling such as providing referrats for HIV testing agencies, enhancing perception of risk, exploring risk incidents and contributing referrats for HIV testing agencies, enhancing perception of risk, exploring risk incidents and contributing referrats for HIV testing agencies, enhancing perception of risk, exploring risk incidents and contributing referrats for HIV testing agencies, enhancing perception of risk, exploring risk incidents and contributing referrats for HIV testing agencies, enhancing perception of risk, exploring risk incidents and contributing referrats for HIV testing agencies, enhancing perception of risk, exploring risk incidents and contributing referrats for HIV testing agencies, enhancing perception of risk, exploring risk incidents and contributing referrats for HIV testing agencies, enhancing perception of risk, exploring risk incidents and contributing referrats for HIV testing agencies, enhancing perception of risk, exploring risk incidents and contributing referrats for HIV testing agencies, enhancing perception of risk, exploring risk inciden	 Introduc 	e self, inquire a	about	visit experier	nce.										
 Provide testing: if accepted, review consent process, participant sign to and date consent: counselor to sign consent: if testing rejected, probe for reasons: strategize ways to overcome obstacles; if testing still rejected, probe for reasons: strategize ways to overcome obstacles; if testing still response of month appointment is scheduled; remind participant of payment for contacting staff to verify locating information. [Provide HIV rapid test] 4. Was Rapid HIV testing conducted? [Rapid HIV testing conducted] 5. Provide content beyond ARM 2 script: Did counselor provide ARM 1 content or other non-scripted material or counseling such as providing referrals for HIV testing agencies, enhancing perception of risk, exploring risk incident and contributing raters (substance use, etc), reviewing previous risk reduction strategies, summarizing risk incident and participant to get tested, or other information or counseling not in ARM 2 script. [Provided content beyond ARM 2 script:] 	Collectin immedia	g fingerstick sa tely if invalid o	imple; r react	testing time tive; confider				o retest							
 [Rapid HIV testing conducted] [N:0] [FRPR204a] No If NO, STOP Session [N:1] Participant did not accept rapid HIV testing [N:2] Participant did not sign HIV Informed Consent for rapid HIV testing [N:1] Yes [N:1] Yes [FRPR205] [RateScale] 	 Provide t consent; rejected ensure 6 locating 	esting: if acce if testing reject see about rem month appoin information.	oted, r ted, p naining tment	orobe for reas g study activi	sons; strategize ities (STD spec	e ways to over imen collection	come obstacles; if testing , clinician visit, exit inter	y still view);							
Did counselor provide ARM 1 content or other non-scripted material or counseling such as providing referrals for HIV testing agencies, enhancing perception of risk, exploring risk incidents and contributing factors (substance use, etc), reviewing previous risk reduction strategies, summarizing risk incident and pattern, negotiating a risk reduction plan, identifying sources of support, motivating participant to get tested, or other information or counseling not in ARM 2 script. [RateScale] >> [Provided content beyond ARM 2 script:] [Provided content beyond ARM 2 script:]		* 4. Was Rapid HIV testing conducted?								[N:0] [FRPR204a] No [N:1] Participant did not accept rapid HIV testing If NO, STOP Session [N:2] Participant did not sign HIV Informed Consent for rapid HIV testing [N:3] Participant did not return for results session					
Key: [*] = Item is required [🗸] = Source verification required	Did counselor provide ARM 1 content or other non-scripted material or counseling such as providing referrals for HIV testing agencies, enhancing perception of risk, exploring risk incidents and contributing factors (substance use, etc), reviewing previous risk reduction strategies, summarizing risk incident and pattern, negotiating a risk reduction plan, identifying sources of support, motivating participant to get tested, or other information or counseling not in ARM 2 script.														
	Key: [*] = It	em is required [✔] =	Source verifica	ation required				·						

Codelist Values and Tables: ARM 2-FINGERSTICK RAPID PRE-RESULTS SESSION

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
RateScale	Integer	Not At All	0	ciNTATALL	FRPR201,
		Somewhat	1	ciSomewhat	FRPR202, FRPR203,
		Mostly	2	ciMostly	FRPR205
		Completely	3	ciCompletely	
					1

A١	WARE_RATE	ARE_RATER: ARM 2-FINGERSTICK RAPID RESULTS SESSION-NEGATIVE RESULTS (FRRN2) - Repeating Form [frFRRN2]												
#	Participant ID#:	Session Date:	Review Date:	Session Length	Reviewer #:	Immediately provide test results:	Remind participant of window period of test: Close session: Provided content beyond ARM 2	2						
1														
· [:	stFRRN21]													
1.* ✔	Participant ID#	÷:]					[FRRN2PID] N4							
2.* ✓	Session Date: [Session Date:]						[FRRN2SDT] Req V / Req V (2010-2012)							
3.* ✔	Review Date: [Review Date:]						[FRRN2EDT] Req V / Req V / Req V (2010-2012)							
4.* ✓	Session Length [Session Length						[FRRN2MM] N3 mins							
5.* ✓	Reviewer #: [Reviewer #:]						[FRRN2REV] N4							
То	what extent die	d the counseld	or: [stFRRN22]										
6. [*] ✔	1. Immediately Test result is ne [Immediately p	gative.					[FRRN201] [RateScale]							
7.* ✓	2. Remind parti Take 2 weeks to months; retesti [Remind partici	o 6 months for ng should occu	HIV antibodies r at 3 months fr	to develop, maj rom most recent		levelop antibodies within 3	[FRRN202] [RateScale]							
8.* ✓	Thank participa	nt for study par ayment for con collection, clini	tacting staff to	verify locating ir		i is scheduled; remind ew remaining study activities	[FRRN203] [RateScale]							
9.* ✓	Did counselor p counseling cont exploring risk in strategies, sum	rovide ARM 1 p ent such as pro- ncidents and co marizing risk in ng referrals, de results sessior	pre-results or re poviding referrral ntributing facto ncident and patt emonstrating pr n script?	s for HIV testing rs (substance us ern, negotiating	g agencies, enha se, etc), reviewi j a risk reductioi	non-scripted material or incing perception of risk, ng previous risk reduction n plan, identifying sources of formation or counseling not in	[FRRN204] [RateScale]							
к	Key: [*] = Item is r													

Codelist Values and Tables: ARM 2-FINGERSTICK RAPID RESULTS SESSION-NEGATIVE RESULTS Codelist RefName Codelist Data Type Label Code Codelist Item RefName Data Variable RefName RateScale 0 FRRN201, Integer Not At All ciNTATALL FRRN202, 1 Somewhat ciSomewhat FRRN203, FRRN204 2 ciMostly Mostly Completely 3 ciCompletely 95 ciNTRATED Not Rated

A٧	WARE_RATER: ARM 2-FINGERSTICK RAPID RESULTS SESSION-INVALID RESULTS (FRRI2) - Repeating Form [frFRRI2]												
#	Participant ID#:	Session Date:	Review Date:	Session Length	Reviewer #:	Immediately provide test result and meaning of result:	Explore reaction to invalid test result:	Remind participant of need for immediate retestin	Examine testing process and readiness to be retested; retest:				
1													
. [s	tFRRI21]												
1.* ✔	Participant ID [Participant II						[FRRI 2PI D] N4						
2.* ✔	Session Date: [Session Date	:]					[FRRI 2SDT] Req 💽 / Req 💽 / Req 🔽	(2010-2012)					
3.* ✔	Review Date: [Review Date]					[FRRI 2EDT] Req • / Req •	(2010-2012)					
4. [*] ✔	Session Lengt [Session Leng						[FRRI 2MM] N3 mins						
5.* ✓	Reviewer #: [Reviewer #:]						[FRRI 2REV]						
То	what extent of	lid the cour	selor: [stFl	RRI 22]									
6. [*] ✔	1. Immediate Test result is sample proces [Immediately	nvalid; mear ssing.	ns we do not	know the res	ult; could be	problem with: test kit, sample collection,	[FRRI 201] [RateScale]						
	2. Explore rea Apologize for retested). [Explore react	unfortunate	experience;	examine feelir	ngs, thoughts	around invalid test result; (and need to be	[FRRi 202] [RateScale]						
8.* ✓	3. Remind part Need to collect [Remind parti	t another fin	gerstick rapi	d sample imm		ults will be ready in 20 minutes.	[FRRI 203] [RateScale]						
9.* ✔	4. Examine testing process and readiness to be retested; retest: Explain the retesting process; inquire if any further questions, comments before retesting; explore waiting for results (again) and strategize coping plan during wait period; proceed with retesting; IF refusing further testing: strategize some testing: oral confirmatory or schedule testing appointment. [Examine testing process and readiness to be retested; retest:]												
Ke	y: [*] = Item i	s required [🗸] = Source ve	erification requi	red		1						

Codelist Values and Tables: ARM 2-FINGERSTICK RAPID RESULTS SESSION-INVALID RESULTS

Codelist RefName	Codelist Data Type	Label	Code	Codelist I tem RefName	Data Variable RefName		
RateScale	Integer	Not At All	0	ciNTATALL	FRRI201,		
		Somewhat	1	ciSomewhat	FRRI202, FRRI203,		
		Mostly	2	ciMostly	FRRI204		
		Completely	3	ciCompletely			
		Not Rated	95	ciNTRATED			

ID#:	Date:	Date:	Length	Reviewer #:	Immediately provide test result and meaning of result:	Explore reaction to reactive test result:	If not already collected: Remind participant of need for immediate retesting:	Examine readiness for further testing and conduct additional testing:	Assess coping ability/need for additional support:	Assist participant in making a plan for self car	Arrange for counselor care call:	Broach risk reduction to self and others:	Stress importance of returning for	
+EDSD211														
Participan								[FRSR2PID] N4						
								[FRSR2SDT] Req 💽 / Req 💽 / Re	eq 💽 (2010-2012)					
									eq 🔽 (2010-2012)					
								[FRSR2MM] N3 mins						
	Reviewer #:]													
what exten	t did the	counseld	or: [stFRS	R22]										
is needed.														
Feelings, t	houghts,	questions	around re	active test	result; reassure partic	cipant staff is a		[FRSR202] [RateScale]						
Will collect for confirm	t venous k natory res	olood conf ults.	irmatory t	est; results	ready in about two w	eeks; will be s	cheduled to return	[FRSR203] [RateScale]						
Inquire if a strategize testing: or	any furthe plan durii ral confirm	er question ng wait pe natory or s	ns, comme eriod; PRO schedule t	ents before CEED with esting appo	further testing; exploi TESTING. IF refusing t intment.		esults (again) and	[FRSR204] [RateScale] 💽						
Provide su brainstorn	ipport; as: n strategie	sess for se es to avoid	elf-harm (a d self-harn	and harm to n and subst	o others); and assess ance use; provide refe			[FRSR205] [RateScale]						
Make a pla call to frie	an for toda nd/family	ay, after li from offic	eaving the	office; ider		ould be suppor		[FRSR206] [RateScale]						
 * 7. Arrange for counselor care call: Provide care call; schedule call; encourage participant to come to study office visit during the week if needed. [Arrange for counselor care call:] 								[FRSR207] [RateScale]						
Explain im	portance	of reducir	ng risk to s	elf and oth	ers; explore possibility	y of putting oth		[FRSR208] [RateScale]						
							[FRSR209] [RateScale]							
	 [Participar [Participar Session D [Session D [Session D [Review Da [Review Da [Review Da [Review Da Session Le [Session Le [Inducedation Lession Le [Inducedation Lession Lession Le [Inducedation Lession Lession Lession Lession Le [Inducedation Lession Lessio	Participant ID#: [Participant ID#:] Session Date: [Session Date:] Review Date: [Review Date:] Session Length: [Session Length: [Session Length] Reviewer #: [Reviewer #:] what extent did the 1. Immediately provic 2. Explore reaction to 3. If not already colle Will collect venous to for confirmatory ress [If not already colle 4. Examine readiness * 5. Assess coping ab Provide support; ass brainstorm strategie [Assess coping abilit * 6. Assist participant in * 7. Arrange for counse * 8. Broach risk reduce [Broach risk reduce] [Broach risk reduce] [B	Participant ID#: [Participant ID#:] Session Date: [Session Date:] Review Date: [Review Date:] Session Length: [Session Length] Reviewer #: [Reviewer #:] what extent did the counselor 1. Immediately provide test rest rest result is reactive; antibo is needed. [Immediately provide test rest? 2. Explore reaction to reactive feelings, thoughts, questions [Explore readiness for further 4. Examine readiness for further 4. Examine readiness for further 5. Assess coping ability/need for 4. Assist participant in making Make a plan for today, after he call to friend/family from offic [Assist participant in making Make a plan for counselor care Provide care call; schedule ca needed. [Arrange for counselor care ca 8. Broach risk reduction to set Explain importance of reducir [Broach risk reduction to set Secure commitment from par receive result; result; have par secure commitment from par receive result; result; have par secure result; result; have par secure can set for to the feeling secure commitment from par receive result; result; have par secure commitment from par secure commitment from par secure commitment from par secure result; result; have par	Participant ID#: [Participant ID#:] Session Date: [Session Date:] Review Date:] Session Length: [Session Length] Reviewer #:] What extent did the counselor: [stFRS 1. Immediately provide test result and Test result is reactive; antibodies to HIV is needed. [Immediately provide test result and m 2. Explore reaction to reactive test result 3.If not already collected: Remind partic Will collect venous blood confirmatory t for confirmatory results. [If not already collected: Remind partic 4. Examine readiness for further testing Inquire if any further questions, comme strategize plan during wait period; PRO testing: oral confirmatory or schedule t [Examine readiness for further testing at 5. Assess coping ability/need for addition 4. 6. Assist participant in making a plan for 5. Assess coping ability/need for addition 5. Assess	Participant ID#: [Participant ID#:] Session Date: [Session Date:] Review Date: [Review Date:] Session Length: [Session Length] Reviewer #: [Reviewer #:] what extent did the counselor: [stFRSR22] 1. Immediately provide test result and meaning of Test result is reactive; antibodies to HIV were detais needed. [Immediately provide test result and meaning of rest result is reaction to reactive test result: 7. Explore reaction to reactive test result: Seligns, thoughts, questions around reactive test [Explore reaction to reactive test result:] 3.1f not already collected: Remind participant of new Will collect venous blood confirmatory test; results for confirmatory results. [If not already collected: Remind participant of new Will collect venous blood confirmatory test; results for confirmatory results. [If not already collected: Remind participant of new Will collect venous blood confirmatory test; results for confirmatory results. [If not already collected: Remind participant of new Will collect venous blood confirmatory test; results for confirmatory results. [If not already collected: Remind participant of new Will collect venous blood confirmatory test; results for confirmatory or schedule testing apped [Examine readiness for further testing and conduct] * 5. Assess coping ability/need for additional support]	Image: Second	Image: Section Date: result: result: Image: Section Date: Section Date: Section Date: Section Length: Section Length: Section Date: Section Length: Section Length: Section Length: Section Length: Section Length: Section Length: Section Length: Section Length: Section Length: I. Immediately provide test result and meaning of result: Total Section Length: Test result is reactive: antibodies to HIV were detected; small chance of false positive tis is needed. Immediately provide test result: 1. Immediately provide test result: and meaning of result: Section to reactive test result: 2. Explore reaction to reactive test result: Section to reactive test result: 3.1 fn at already collected: Remind participant of need for immediate retesting: Inquire if any further questions, comments before further testing; explore waiting for r strategize plan during wait period; PROCEED with TESTING. IF refusing furt	Image: Section 10 and	Image: Season Date: Image: Season Date:	Line Line <thlin< th=""> Line Line L</thlin<>	Image: biology of the second and maning of result: result: ror immediate retexting: and conduct additional testing: support: For self car additional testing: Image: biology of the second and the second additional testing: Image: biology of the second additional testing: Image: biology of the second additional testing: Image: biology of the second additional testing: Image: biology of the second additional testing: Image: biology of the second additional testing: Image: biology of the second additional testing: Image: biology of the second additional testing: Image: biology of the second additional testing: Image: biology of the second additional testing: Image: biology of the second additional testing: Image: biology of the second additional testing: Immediately provide test result: Image: biology of the second additional testing: Image: biology of the second additiona	Image: Second Participant Second Partimater Second Participant Second Participant Second Participant Sec	Image: Image:<	

Codelist Values	Codelist Values and Tables: ARM 2-FINGERSTICK RAPID RESULTS SESSION-REACTIVE RESULTS											
Codelist RefName	Codelist Data Type	Label	Code	Codelist I tem RefName	Data Variable RefName							
RateScale	Integer	Not At All	0	CINTATALL	FRSR201, FRSR202.							
		Somewhat	1	ciSomewhat	FRSR203,							
		Mostly	2	ciMostly	FRSR204, FRSR205,							
		Completely	3	ciCompletely	FRSR206, FRSR207,							
		Not Rated	95	ciNTRATED	FRSR208, FRSR209							