Annotated Study Book for Study Design: AWARE_RATER

Study Design Version: 1.0

AWARE RATER

Generated by Central Designer ™

May 11, 2010 2:58PM

	Time and Events Schedule For Study Design: AWARE_RATER						
	Element		System				
	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					3-RF
11	ARM 2-FINGERSTICK RAPID RESULTS SESSION-REACTIVE RESULTS	FRSR2					4-RF
	Key: [S] = Scheduled Visit [D] = Dynamic Visit [U] = Unscheduled Visit [R] = Repeating Visit C = Common Form DF = Dynamic Form RF = Repeating Form						

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

AWARE_RATER: ENROLLMENT (ENR) [frENR]

1.* ✔	Counselor Number [Counselor Number]	**[ENRCOUN]** A13

Key: [*] = Item is required [✔] = Source verification required

AWARE_RATER: Counselor Information (CI) [frCI]	
. [stCI]	
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.	
1.* ✔ Counselor Number [Counselor Number]	[ENRCOUN] A13
Key: [*] = Item is required [✔] = Source verification required	

AWARE_RATER: ARM 1-PRE-RESULTS SESSION (PRS1) - Repeating Form [frPRS1]

#	Participant ID#:	Session Date:	Review Date:	Session Length	Reviewer #:	Provide an introduction:	Frame HIV conseling session	Provide general testing information	Provide HIV rapid test	Enhance participant's perception of risk	Assess for risk and contributing factors:	Identify client's ambivalence risk behavior	Examin previous risk reduction	summarize risk, factors, readiness for change:	Negotiate risk reduction plan	Identify sources of support for participant's risk reduction plan	Rapid HIV testing conducted
1																	

. [stPRS1]

1.* ✔	Participant ID#: [Participant ID#:]	[PRS1PTID] N4
2.* ✔	Session Date: [Session Date:]	[PRS1STDT] Req ▼ / Req ▼ / Req ▼ (2010-2012)
3.* ✔	Review Date: [Review Date:]	[PRS1EDT] Req ▼ / Req ▼ / Req ▼ (2010-2012)
4.* ✔	Session Length: [Session Length]	[PRS1MM] N3 mins
5.* ✔	Reviewer #: [Reviewer #:]	[PRS1REV] N4

To what extent did the counselor: [stPRS12]

6.* ✔	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:]	[PRS101] [RateScale] ▼
7.* ✔	2. Frame HIV counseling session: Share information about rapid HIV test; provide HIV test; discuss possible risk behaviors for HIV and other STDs; create a risk reduction plan; provide information about the HIV test and test results. [Frame HIV conseling session]	[PRS102] [RateScale] ▼
8.* ✔	3. Provide general testing information: Type and time of test, possible results of test, need for immediate additional testing if for invalid or reactive results; further questions around testing. [Provide general testing information]	[PRS110] [RateScale] ▼
9.* ✔	4. Provide HIV rapid test: Provide testing: review consent process, have participant sign and date consent; counselor sign consent. If testing rejected, probe for reasons; strategize ways to overcome obstacles; continue with risk reduction counseling. [Provide HIV rapid test]	[PRS111] [RateScale] ▼
10.* ✔	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 behavior. [Enhance participant's perception of risk]	[PRS103] [RateScale] ▼
11.* ✔	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:]	[PRS104] [RateScale] ▼
12.* ✔	7. 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]	[PRS105] [RateScale] ▼
13.* ✔	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.* ✔	11. 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: [*] = Item is required [✔] = Source verification required

Codelist Values and Tables: ARM 1-PRE-RESULTS SESSION

Codelist RefName	Codelist Data Type	Label	Code	Codelist Item RefName	Data Variable RefName
RateScale	Integer	Not At All	0	ciNTATALL	PRS101, PRS102, PRS110, PRS111, PRS103, PRS104, PRS105, PRS106, PRS107, PRS108, PRS109
		Somewhat	1	ciSomewhat	
		Mostly	2	ciMostly	
		Completely	3	ciCompletely	
		Not Rated	95	ciNTRATED	

AWARE_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:
1												

. [stFRRN11]		
1.* ✔	Participant ID#: [Participant ID#:]	**[FRRN1PID]** N4
2.* ✔	Session Date: [Session Date:]	**[FRRN1SDT]** Req ⌄ / Req ⌄ / Req ⌄ (2010-2012)
3.* ✔	Review Date: [Review Date:]	**[FRRN1EDT]** Req ⌄ / Req ⌄ / Req ⌄ (2010-2012)
4.* ✔	Session Length: [Session Length]	**[FRRN1MM]** N3 mins
5.* ✔	Reviewer #: [Reviewer #:]	**[FRRN1REV]** N4
To what extent did the counselor: [stFRRN12]		
6.* ✔	1. Immediately provide test results: Test result is non-reactive (negative). [Immediately provide test results:]	**[FRRN101]** **[RateScale]** ⌄
7.* ✔	2. Explore reaction to negative test result: Feeling, thoughts around negative test result. [Explore reaction to negative test result:]	**[FRRN102]** **[RateScale]** ⌄
8.* ✔	3. Remind participant of window period of test: Takes 2 weeks to 6 months for HIV antibodies to develop; majority of people develop antibodies within 3 months; retesting should occur at 3 months from most recent exposure; need to protect self and sexual partners. [Remind participant of window period of test:]	**[FRRN103]** **[RateScale]** ⌄
9.* ✔	4. Revisit risk reduction plan: Discuss possible impact of negative test results on future sexual/substance use behavior; support plan; explore ways participant can receive support for plan from others. [Revisit risk reduction plan]	**[FRRN104]** **[RateScale]** ⌄
10.* ✔	5. Address tough-to-manage issues: Thoughts about professional support (clinic staff or others) for specific issues; sources for professional assistance. [Address tough-to-manage issues:]	**[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:]	**[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:]	**[FRRN107]** **[RateScale]** ⌄

Key: [*] = Item is required [✔] = Source verification required

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

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

		Completely	3	ciCompletely	FRRN106, FRRN107
		Not Rated	95	ciNTRATED	

AWARE_RATER: ARM 1-FINGERSTICK RAPID RESULTS SESSION-INVALID RESULTS (FRRI1) - Repeating Form [frFRRI1]

#	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:
1									

. [stFRRI1]

1.* ✔	Participant ID#: [Participant ID#:]	**[FRRI1PID]** N4
2.* ✔	Session Date: [Session Date:]	**[FRRI1SDT]** Req ▼ / Req ▼ / Req ▼ (2010-2012)
3.* ✔	Review Date: [Review Date:]	**[FRRI1EDT]** Req ▼ / Req ▼ / Req ▼ (2010-2012)
4.* ✔	Session Length: [Session Length]	**[FRRI1MM]** N3 mins
5.* ✔	Reviewer #: [Reviewer #:]	**[FRRI1REV]** N4

To what extent did the counselor: [stFRRI12]

6.* ✔	1. Immediately provide test result and meaning of result: Test result is invalid; means we do not know the result; could be problem with: test kit, sample collection, sample processing. [Immediately provide test result and meaning of result:]	**[FRRI101]** **[RateScale]** ▼
7.* ✔	2. Explore reaction to invalid test result: Apologize for unfortunate experience; examine feelings, thoughts about invalid test result and need to be retested. [Explore reaction to invalid test result:]	**[FRRI102]** **[RateScale]** ▼
8.* ✔	3. Remind participant of need for immediate retesting: Need to collect another fingerstick rapid sample immediately; results will be ready in 20 minutes. [Remind participant of need for immediate retesting:]	**[FRRI103]** **[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:]	**[FRRI104]** **[RateScale]** ▼

Key: [*] = Item is required [✔] = Source verification required

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

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

AWARE_RATER: ARM 1-FINGERSTICK RAPID RESULTS SESSION-REACTIVE RESULTS (FRRR1) - Repeating Form [frFRRR1]

#	Participant ID#:	Session Date:	Review Date:	Session Length	Reviewer #:	Immediately provide test result and meaning of result:	Explore reaction to reactive test 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:
1														

. [stFRRR11]

1.* ✔	Participant ID#: [Participant ID#:]	**[FRRR1PID]** N4
2.* ✔	Session Date: [Session Date:]	**[FRRR1SDT]** Req ⌄ / Req ⌄ / Req ⌄ (2010-2012)
3.* ✔	Review Date: [Review Date:]	**[FRRR1EDT]** Req ⌄ / Req ⌄ / Req ⌄ (2010-2012)
4.* ✔	Session Length: [Session Length]	**[FRRR1MM]** N3 mins
5.* ✔	Reviewer #: [Reviewer #:]	**[FRRR1REV]** N4

To what extent did the counselor: [stFRRR12]

6.* ✔	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]** ⌄
7.* ✔	2. Explore reaction to reactive test result: Feelings, thoughts, questions around reactive test result; reassure participant staff is available for support. [Explore reaction to reactive test result:]	**[FRRR102]** **[RateScale]** ⌄
8.* ✔	3. Remind participant of need for immediate retesting: Will collect venous blood confirmatory test; results ready in about two weeks; will be scheduled to return for confirmatory results. [Remind participant of need for immediate retesting:]	**[FRRR103]** **[RateScale]** ⌄
9.* ✔	4. Examine readiness for further testing and conduct additional testing: Inquire if any further questions, comments before further testing; explore waiting for results (again) and strategize coping plan during wait period; PROCEED with TESTING. IF refusing further testing: strategize some testing: oral confirmatory or schedule testing appointment. [Examine readiness for further testing and conduct additional testing:]	**[FRRR104]** **[RateScale]** ⌄
10.* ✔	5. Assess coping ability/need for additional support: Provide support; assess for self-harm (and harm to others); and assess for impulse to use substances and brainstorm strategies to avoid self-harm and substance use; provide referrals. [Assess coping ability/need for additional support:]	**[FRRR105]** **[RateScale]** ⌄
11.* ✔	6. Assist participant in making a plan for self care: Make a plan for today, after leaving the office; identify person(s) who would be supportive; offer to make call to friend/family from office. [Assist participant in making a plan for self care:]	**[FRRR106]** **[RateScale]** ⌄
12.* ✔	7. Arrange for counselor care call: Provide care call; schedule call; encourage participant to come to study office during the week, IF needed. [Arrange for counselor care call:]	**[FRRR107]** **[RateScale]** ⌄
13.* ✔	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:]	**[FRRR108]** **[RateScale]** ⌄
14.* ✔	9. Stress importance of returning for confirmatory test result: Secure commitment from participant to return for result; strategize what/who will assist participant to receive result; have participant agree to call if participant is considering not returning for results visit. [Stress importance of returning for confirmatory test result:]	**[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 Item RefName	Data Variable RefName
RateScale	Integer	Not At All	0	ciNTATALL	FRRR101, FRRR102, FRRR103, FRRR104, FRRR105, FRRR106, FRRR107, FRRR108, FRRR109
		Somewhat	1	ciSomewhat	
		Mostly	2	ciMostly	
		Completely	3	ciCompletely	
		Not Rated	95	ciNTRATED	

AWARE_RATER: ARM 2-FINGERSTICK RAPID PRE-RESULTS SESSION (FRPR2) - Repeating Form [frFRPR2]

#	Participant ID#:	Session Date:	Review Date:	Session Length	Reviewer #:	Provide an introduction:	Provide general testing information	Provide HIV rapid test	Rapid HIV testing conducted	Provided content beyond ARM 2 script:
1										

. [stFRPR21]

1.* ✔	Participant ID#: [Participant ID#:]	**[FRPR2PID]** N4
2.* ✔	Session Date: [Session Date:]	**[FRPR2SDT]** Req ⌄ / Req ⌄ / Req ⌄ (2010-2012)
3.* ✔	Review Date: [Review Date:]	**[FRPR2EDT]** Req ⌄ / Req ⌄ / Req ⌄ (2010-2012)
4.* ✔	Session Length: [Session Length]	**[FRPR2MM]** N3 mins
5.* ✔	Reviewer #: [Reviewer #:]	**[FRPR2REV]** N4

To what extent did the counselor: [stFRPR22]

6.* ✔	1. Provide an introduction: Introduce self, inquire about visit experience. [Provide an introduction:]	**[FRPR201]** **[RateScale]** ⌄
7.* ✔	2. Provide general testing information: 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]	**[FRPR202]** **[RateScale]** ⌄
8.* ✔	3. 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]	**[FRPR203]** **[RateScale]** ⌄
9.* ✔	4. Was Rapid HIV testing conducted? [Rapid HIV testing conducted]	**[FRPR204]** *[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 *[N:1]* ◯ Yes
10.* ✔	5. Provided 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 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. [Provided content beyond ARM 2 script:]	**[FRPR205]** **[RateScale]** ⌄

Key: [*] = Item is required [✔] = Source verification 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, FRPR202, FRPR203, FRPR205
		Somewhat	1	ciSomewhat	
		Mostly	2	ciMostly	
		Completely	3	ciCompletely	

		Not Rated	95	ciNTRATED	

AWARE_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 script:
1									

	. [stFRRN21]	
1.* ✔	Participant ID#: [Participant ID#:]	**[FRRN2PID]** N4
2.* ✔	Session Date: [Session Date:]	**[FRRN2SDT]** Req ▼ / Req ▼ / Req ▼ (2010-2012)
3.* ✔	Review Date: [Review Date:]	**[FRRN2EDT]** Req ▼ / Req ▼ / Req ▼ (2010-2012)
4.* ✔	Session Length: [Session Length]	**[FRRN2MM]** N3 mins
5.* ✔	Reviewer #: [Reviewer #:]	**[FRRN2REV]** N4
	To what extent did the counselor: [stFRRN22]	
6.* ✔	1. Immediately provide test results: Test result is negative. [Immediately provide test results:]	**[FRRN2O1]** **[RateScale]** ▼
7.* ✔	2. Remind participant of window period of test: Take 2 weeks to 6 months for HIV antibodies to develop, majority of people develop antibodies within 3 months; retesting should occur at 3 months from most recent exposure. [Remind participant of window period of test:]	**[FRRN2O2]** **[RateScale]** ▼
8.* ✔	3. Close session: Thank participant for study participation; ensure next appointment (6 month) is scheduled; remind participant of payment for contacting staff to verify locating information; review remaining study activities (STD specimen collection, clinician visit, exit interview). [Close session:]	**[FRRN2O3]** **[RateScale]** ▼
9.* ✔	4. Provided content beyond ARM 2 script: Did counselor provide ARM 1 pre-results or results session material or other non-scripted material or counseling content such as providing referrrals 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, providing referrals, demonstrating proper condom usage, or other information or counseling not in ARM 2 negative results session script? [Provided content beyond ARM 2 script:]	**[FRRN2O4]** **[RateScale]** ▼

Key: [*] = Item is required [✔] = Source verification required

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	Integer	Not At All	0	ciNTATALL	FRRN2O1, FRRN2O2, FRRN2O3, FRRN2O4
		Somewhat	1	ciSomewhat	
		Mostly	2	ciMostly	
		Completely	3	ciCompletely	
		Not Rated	95	ciNTRATED	

AWARE_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									

. [stFRRI21]

1.* ✔	Participant ID#: [Participant ID#:]	**[FRRI2PID]** N4
2.* ✔	Session Date: [Session Date:]	**[FRRI2SDT]** Req ▼ / Req ▼ / Req ▼ (2010-2012)
3.* ✔	Review Date: [Review Date:]	**[FRRI2EDT]** Req ▼ / Req ▼ / Req ▼ (2010-2012)
4.* ✔	Session Length: [Session Length]	**[FRRI2MM]** N3 mins
5.* ✔	Reviewer #: [Reviewer #:]	**[FRRI2REV]** N4

To what extent did the counselor: [stFRRI22]

6.* ✔	1. Immediately provide test result and meaning of result: Test result is invalid; means we do not know the result; could be problem with: test kit, sample collection, sample processing. [Immediately provide test result and meaning of result:]	**[FRRI201]** **[RateScale]** ▼
7.* ✔	2. Explore reaction to invalid test result: Apologize for unfortunate experience; examine feelings, thoughts around invalid test result; (and need to be retested). [Explore reaction to invalid test result:]	**[FRRI202]** **[RateScale]** ▼
8.* ✔	3. Remind participant of need for immediate retesting: Need to collect another fingerstick rapid sample immediately; results will be ready in 20 minutes. [Remind participant of need for immediate retestin]	**[FRRI203]** **[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:]	**[FRRI204]** **[RateScale]** ▼

Key: [*] = Item is required [✔] = Source verification required

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

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

AWARE_RATER: ARM 2-FINGERSTICK RAPID RESULTS SESSION-REACTIVE RESULTS (FRSR2) - Repeating Form [frFRSR2]

#	Participant ID#:	Session Date:	Review Date:	Session 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
1														

. [stFRSR21]

1.* ✔	Participant ID#: [Participant ID#:]	**[FRSR2PID]** N4

2.* ✔	Session Date: [Session Date:]	**[FRSR2SDT]** Req ▾ / Req ▾ / Req ▾ (2010-2012)

3.* ✔	Review Date: [Review Date:]	**[FRSR2EDT]** Req ▾ / Req ▾ / Req ▾ (2010-2012)

4.* ✔	Session Length: [Session Length]	**[FRSR2MM]** N3 mins

5.* ✔	Reviewer #: [Reviewer #:]	**[FRSR2REV]** N4

To what extent did the counselor: [stFRSR22]

6.* ✔	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 test is needed. [Immediately provide test result and meaning of result:]	**[FRSR201]** [RateScale] ▾

7.* ✔	2. Explore reaction to reactive test result: Feelings, thoughts, questions around reactive test result; reassure participant staff is available for support. [Explore reaction to reactive test result:]	**[FRSR202]** [RateScale] ▾

8.* ✔	3.If not already collected: Remind participant of need for immediate retesting: Will collect venous blood confirmatory test; results ready in about two weeks; will be scheduled to return for confirmatory results. [If not already collected: Remind participant of need for immediate retesting:]	**[FRSR203]** [RateScale] ▾

9.* ✔	4. Examine readiness for further testing and conduct additional testing: Inquire if any further questions, comments before further testing; explore waiting for results (again) and strategize plan during wait period; PROCEED with TESTING. IF refusing further testing, strategize some testing: oral confirmatory or schedule testing appointment. [Examine readiness for further testing and conduct additional testing:]	**[FRSR204]** [RateScale] ▾

10.* ✔	5. Assess coping ability/need for additional support: Provide support; assess for self-harm (and harm to others); and assess for impulse to use substances and brainstorm strategies to avoid self-harm and substance use; provide referrals. [Assess coping ability/need for additional support:]	**[FRSR205]** [RateScale] ▾

11.* ✔	6. Assist participant in making a plan for self care: Make a plan for today, after leaving the office; identify person(s) who would be supportive; offer to make call to friend/family from office. [Assist participant in making a plan for self car]	**[FRSR206]** [RateScale] ▾

12.* ✔	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] ▾

13.* ✔	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:]	**[FRSR208]** [RateScale] ▾

14.* ✔	9. Stress importance of returning for confirmatory test result: Secure commitment from participant to return for result; strategize what/who will assist participant to receive result; result; have participant agree to call if participant may not return for results visit. [Stress importance of returning for]	**[FRSR209]** [RateScale] ▾

Key: [*] = Item is required [✔] = Source verification required

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