

## STUDY ENROLLMENT (ENR)

NIDA-CTN-0015	Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial		Seq. Num.: __ __
NODE: __ __	STUDY Visit: (circle one)	Screening EPOCH VISITNUM	
CTP-SITE ID: __ __ - __ __			
PARTICIPANT ID: __ __ USUBJID			
Assessment Date: __ __ / __ __ / __ __ SCDTC (mm / dd / yyyy)		STAFF ID: __ __ __ __	
__ FORM COMPLETION STATUS	1=CRF Administered 2=Participant refused 3=Staff Member did not Administer		4=Not enough time to Administer 5=No Participant Contact 6=Other

(Research Assistant/Independent Assessor Completed)

## SCTEST

## SCORRES

1. Date informed consent was signed: \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ (mm / dd / yyyy)

NOTE: Boxed annotations indicate supplemental qualifier variables. Result found in QVAL field.

## DEMOGRAPHICS (DEM)

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NIDA-CTN-0015		Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial		Seq. Num.: ____	
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CTP-SITE ID: ____ - ____					
PARTICIPANT ID: ____ <b>USUBJID</b>					
Assessment Date: ____ / ____ / ____ (mm / dd / yyyy)			STAFF ID: ____		
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(Research Assistant/Independent Assessor Completed)

## DEMOGRAPHICS

1. Sex: **DM.SEX**  
 1 = Male  
 2 = Female

2. Date Of Birth: **DM.BRTHDTC**  
 m m d d y y y y

3. a. Ethnicity: **DM.ETHNIC**  
 1=Spanish origin, Hispanic or Latino  
 2=Not of Spanish origin, Hispanic or Latino (skip to question 4)

b. If Hispanic or Latino, for each of the following, please circle '1' for 'Yes' or '0' for 'No'.

No	Yes	
0	1	1. Mexican, Mexican-American, or Chicano
0	1	2. Puerto Rican
0	1	3. Cuban
0	1	4. Hispanic or Latino, other (specify) _____

QNAM=SOTHERS  
 QLABEL=SPANISH, HISPANIC, OR LATINO: OTHER TEXT  
 IDVAR=SCSEQ

4. Race: For each of the following, please circle '1' for 'Yes' or '0' for 'No'. Circle '1' for items 'g' or 'h' if participant chooses not to answer or race is unknown. For those categories with further specification, please respond to all sub-category questions. Answer 'Yes' to at least one sub-category. If sub-category is unknown, select 'Other' for the sub-category and write 'Unknown' for the specify.

No	Yes	Race
----	-----	------

0	1	4.a. American Indian or Alaska Native
---	---	---------------------------------------

0	1	4.b. Asian (If 'Yes', please complete 4.b.1 through 4.b.7, if 'No', please skip to question 4.c.)
---	---	---

No	Yes	DM.RACE (If multiple, then = 'MULTIPLE')
----	-----	--

0	1	4.b.1. Asian-Indian
---	---	---------------------

0	1	4.b.2. Chinese
---	---	----------------

0	1	4.b.3. Filipino
---	---	-----------------

0	1	4.b.4. Japanese
---	---	-----------------

0	1	4.b.5. Korean
---	---	---------------

0	1	4.b.6. Vietnamese
---	---	-------------------

0	1	4.b.7. Asian, other (specify) _____
---	---	-------------------------------------

QNAM=AOTHERS  
 QLABEL=ASIAN: OTHER TEXT  
 IDVAR=SCSEQ

0	1	4.c. Black or African American
---	---	--------------------------------

0	1	4.d. Native Hawaiian or Pacific Islander (If 'Yes', please complete 4.d.1 through 4.d.4, if 'No', please skip to question 4.e.)
---	---	---

No	Yes	
----	-----	--

0	1	4.d.1. Native Hawaiian
---	---	------------------------

0	1	4.d.2. Guamanian or Chamorro
---	---	------------------------------

0	1	4.d.3. Samoan
---	---	---------------

0	1	4.d.4. Native Hawaiian or Pacific Islander, other (specify) _____
---	---	---

QNAM=NOTHERS  
 QLABEL=NATIVE HAWAIIAN OR  
 PACIFIC ISLANDER: OTHER TEXT  
 IDVAR=SCSEQ

0	1	4.e. White
---	---	------------

0	1	4.f. Other (specify) _____
---	---	----------------------------

1		4.g. Participant chooses not to answer
---	--	--

1		4.h. Unknown
---	--	--------------

QNAM=OOTHERS  
 QLABEL=ETHNICITY/RACE: OTHER TEXT  
 IDVAR=SCSEQ

SCTEST  
 SCORRES

CTP - Site ID ____-____	Participant ID <u><b>USUBJID</b></u>	Assessment Date: ____ / ____ / <b>SUDTC</b> m m     d d     y y y y
----------------------------	---	--

5. **DRUG USE:** For each of the following substances, please indicate whether the substance has been used in the past 30 days. Also indicate whether the substance was ever administered by injection (IV or Non-IV).

SUROUTE

SUTRT SUDUR		A. PAST 30 DAYS			B. EVER BY INJECTION		
SUBSTANCE		NO	YES	NOT ASSESSED	NO	YES	NOT ASSESSED
1.	Alcohol (any use at all)	0	1	9			
2.	Alcohol (to intoxication)	0	1	9			
3.	Heroin	0	1	9	0	1	9
4.	Methadone/LAAM (prescribed)	0	1	9	0	1	9
5.	Methadone/LAAM (illicit)	0	1	9	0	1	9
6.	Other Opiates/Analgesics	0	1	9	0	1	9
7.	Barbiturates	0	1	9	0	1	9
8.	Other Sedatives/Hypnotics/Tranquilizers	0	1	9	0	1	9
9.	Cocaine	0	1	9	0	1	9
10.	Amphetamines	0	1	9	0	1	9
11.	Cannabis	0	1	9	0	1	9
12.	Hallucinogens	0	1	9	0	1	9
13.	Inhalants	0	1	9	0	1	9
14.	Nicotine (tobacco products)	0	1	9			
15.	More than 1 substance per day (including alcohol, excluding nicotine)	0	1	9	0	1	9

SUTRT

- Printed: 9/22/2003 2:17 PM

# LIFE EVENTS CHECKLIST (LEC) =QSCAT

DOMAIN: QS

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STUDYID

<b>NIDA-CTN-0015</b>		<b>Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial</b>		<b>Seq. Num.: __ __</b>
<b>NODE:</b> ____		<b>VISITNUM</b>	<b>EPOCH</b>	
<b>CTP-SITE ID:</b> ____ - ____		<b>STUDY Visit:</b> (circle one)	Screening	
<b>PARTICIPANT ID:</b> <b>USUBJID</b>				
<b>Assessment Date:</b> ____ / <b>QSDTC</b> ____ (mm / dd / yyyy)			<b>STAFF ID:</b> ____ <b>QSEVAL</b> ____	
<b>FORM COMPLETION STATUS</b>		1=CRF Administered 2=Participant refused 3=Staff Member did not Administer 4=Not enough time to Administer 5=No Participant Contact 6=Other		

(Research Assistant/Independent Assessor Completed)

I am going to read a list of difficult or stressful things that sometimes happen to people. For each event I read, please tell me whether or not it happened to you, you witnessed it or you learned about it. Be sure to consider your entire life (growing up, as well as adulthood) as we go through the list of events.

QSTESTCD/QSTEST

QSORRES

Event		a. Happened to me		b. Witnessed it		c. Learned about it		d. No/ Not sure	
		Yes	No	Yes	No	Yes	No	Yes	No
1.	Natural disaster (for example, flood, hurricane, tornado, earthquake)	1	0	1	0	1	0	1	0
2.	Fire or explosion	1	0	1	0	1	0	1	0
3.	Transportation accident (for example, car accident, boat accident, train wreck, plane crash)	1	0	1	0	1	0	1	0
4.	Serious accident at work, home, or during recreational activity	1	0	1	0	1	0	1	0
5.	Exposure to toxic substance (for example, dangerous chemicals, radiation)	1	0	1	0	1	0	1	0
6.	Physical assault (for example, being attacked, hit, slapped, kicked, beaten up)	1	0	1	0	1	0	1	0
7.	Assault with a weapon (for example, being shot, stabbed, threatened with a knife, gun, bomb)	1	0	1	0	1	0	1	0
8.	Sexual assault (rape, attempted rape, made to perform any type of sexual act through force or threat of harm)	1	0	1	0	1	0	1	0
9.	Other unwanted or uncomfortable sexual experience	1	0	1	0	1	0	1	0
10.	Combat or exposure to a war-zone (in the military or as a civilian)	1	0	1	0	1	0	1	0
11.	Captivity (for example, being kidnapped, abducted, held hostage, prisoner of war)	1	0	1	0	1	0	1	0
12.	Life-threatening illness or injury	1	0	1	0	1	0	1	0
13.	Severe human suffering If yes, specify _____	1	0	1	0	1	0	1	0
14.	Sudden, violent death (for example, homicide, suicide)	1	0	1	0	1	0	1	0
15.	Sudden, unexpected death of someone close to you	1	0	1	0	1	0	1	0
16.	Serious injury, harm, or death you caused to someone else	1	0	1	0	1	0	1	0
17.	Any other very stressful event or experience If yes, specify _____	1	0	1	0	1	0	1	0



**BRIEF CODING INSTRUCTIONS FOR THE CIDI CRF**  
(To be attached to the back of the CRF)

**ALCOHOL**

Column A	If both J1=1 and J1A = 1 (never had 12+ drinks)	Circle "1" AND skip to Drug Section
	If either J1=5 or J1A = 5	Circle "5" and continue with Column B
	If Interviewer Error	Circle "N" and skip to Drug Section
Column B	If J10 is coded "5" (Yes) (i.e., at least one "5" coded in J6-J9)	Circle "5" Yes, continue with Column C
	If J10 is coded "1" (No) (i.e., J6, J7 & 7A, J8, J9 are all "1")	Circle "1" No, skip to Column D
	If Interviewer Error	Circle "N" and skip to Column D
Column C	If column B is coded "5"	Circle the J10 Recency code (1 - 6) in Column C
	If column B is coded "1"	Skip Column C, and go to Column D
	If Interviewer Error	Circle "N"
Column D	If J21 is coded "5"	Circle "5"
	If J21 is coded "1" or blank due to Skip instruction on J20	Circle "1" and go to Drug Section
	If Interviewer Error	Circle "N" and go to Drug Section
Column E	If Column D is coded "5"	Circle the J22 Recency code (1 - 6) in Column E
	If Column D is coded "1"	Skip Columns E and F, and go to Drug section
	If Interviewer Error	Circle "N"
Column F	If J23 is completed AND column D is coded "5"	Circle the J23 Recency code (1 - 6)
	If J23 is not completed, OR if J23 is completed & Column D is coded "1"	Skip Column F and go to the Drug Section
	If Interviewer Error	Circle "N"

**DRUG (repeat for each Drug Category assessed)**

Column A	If column A within the chart in question L4A = 1 for that drug category	Circle "1" AND skip to next Drug category
	If column A within the chart in question L4A = 5 for that drug category	Circle "5" and continue with Column B
	If Interviewer Error	Circle "N" and skip to next drug category
Column B	If L11 is completed for that drug (i.e., at least one "5" coded in L8-L10)	Circle "5" Yes, continue with Column C
	If L11 not completed for that drug (i.e., L8A, L9B, L9C, L10A are all "1")	Circle "1" No, skip to Column D
	If Interviewer Error	Circle "N" and skip to Column D
Column C	If column B is coded "5"	Circle the L11 Recency code (1 - 6) in Column C
	If column B is coded "1"	Skip Column C, and go to Column D
	If Interviewer Error	Circle "N"
Column D	If L22 is coded "5" for that drug category	Circle "5", continue with Column E
	If L22 is coded "1" or blank for that drug category	Circle "1" and go to next drug category
	If Interviewer Error	Circle "N" and go to next drug category
Column E	If Column D is coded "5"	Circle the L22 Recency code (1 - 6) in Column E
	If Column D is coded "1"	Skip Columns E & F, and go to next drug category
	If Interviewer Error	Circle "N"
Column F	If L24 is completed AND column D is coded "5"	Circle the L24 Recency code (1 - 6)
	If L24 not completed, OR if L24 is completed and Column D is coded "1"	Skip Column F and go to the next drug category
	If Interviewer Error	Circle "N"

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<b>CTP-SITE ID:</b> <u>USUBJID</u> ____			
<b>PARTICIPANT ID:</b> ____			
<b>Assessment Date:</b> <u>SUDTC</u> / ____ / ____ (mm / dd / yyyy)		<b>STAFF ID:</b> ____	
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(Research Assistant/Independent Assessor Completed)

SUTRT

SUEVLINT=-P6M

SUOCCUR

1. Did you drink any alcoholic beverage (beer, wine, or liquor) since \_\_\_\_ (0=No, 1=Yes)  
 \_\_\_\_ / \_\_\_\_ / \_\_\_\_ (6 months prior to today's date)?  
 (Enter date above as mm/dd/yyyy)

SUDUR

SUROUTE



## PRISM SUICIDAL AND HOMICIDAL INTENT (PRSM)

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<b>NIDA-CTN-0015</b>	<b>Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial</b>		<b>Seq. Num.:</b> ____
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<b>CTP-SITE ID:</b> ____ - ____			
<b>PARTICIPANT ID:</b> <b>USUBJID</b>			
<b>Assessment Date:</b> ____ / ____ / ____ <b>QSDTC</b> (mm / dd / yyyy)		<b>STAFF ID:</b> ____	
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(Research Assistant/Independent Assessor Completed)

SUICIDALITY **QSTESTCD/QSTEST****QSORRES**

<b>1. Recurrent thoughts of death:</b>						
<ul style="list-style-type: none"> <li>Did you ever find yourself thinking about death or dying? Do you think you would be better off dead?</li> <li>Did you feel as though you wanted to die (did you wish you wouldn't wake up in the morning when you went to bed at night?)</li> <li><b>IF UNCLEAR:</b> Can you describe these thoughts/feelings? How often were you thinking about these things?</li> <li><b>IF YES:</b> Do you still have these thoughts/feelings at the present time? How often? For how long have you been having these thoughts/feelings?</li> </ul>	<ul style="list-style-type: none"> <li>Must have spent some time thinking about death at least three times in a week (not necessarily all day).</li> <li>Include recurrent thoughts that she would be better off dead.</li> <li>Include thoughts of death attributed to health problem or HIV status that occur without a change in health status.</li> <li>Exclude preoccupation with death when someone close is ill or dying, as long as preoccupation is at expected level.</li> <li>Exclude normal fear of death.</li> </ul>	<b>A. Rating Scale:</b> <table border="1"> <tr> <td><b>1</b> (Absent)</td> <td><b>2</b> (Sub-threshold)</td> <td><b>3</b> (Present)</td> </tr> </table>		<b>1</b> (Absent)	<b>2</b> (Sub-threshold)	<b>3</b> (Present)
		<b>1</b> (Absent)	<b>2</b> (Sub-threshold)	<b>3</b> (Present)		
		<b>B. ____</b> 1=Prior to the past 6 months 2=In the past 6 months <b>QSEVLINT</b>				
<b>2. Recurrent suicidal ideation:</b>						
<ul style="list-style-type: none"> <li>Did you ever think about suicide or killing yourself? (What did you think of? How often did you have that thought?)</li> <li><b>IF YES:</b> Do you still think about killing yourself at the present time? How often? For how long have you been having these thoughts?</li> </ul>	<ul style="list-style-type: none"> <li>Must have a thought about this at least three times in a week.</li> <li>Must think actively of killing oneself, even if ambivalent.</li> <li>Can have suicidal ideation without having suicidal plan.</li> </ul>	<b>A. Rating Scale:</b> <table border="1"> <tr> <td><b>1</b> (Absent)</td> <td><b>2</b> (Sub-threshold)</td> <td><b>3</b> (Present)</td> </tr> </table>		<b>1</b> (Absent)	<b>2</b> (Sub-threshold)	<b>3</b> (Present)
		<b>1</b> (Absent)	<b>2</b> (Sub-threshold)	<b>3</b> (Present)		
		<b>B. ____</b> 1=Prior to the past 6 months 2=In the past 6 months				
<b>3. Specific suicide plan</b>						
<ul style="list-style-type: none"> <li>Did you ever think of any specific plan for committing suicide? What did you think of doing?</li> <li><b>IF YES:</b> When was that? For how long did you think of this plan? How often would you think about this plan?</li> <li><b>IF YES:</b> Do you think of any specific plan for committing suicide at the present time? What do you think of doing? How often do you think about it? For how long have you been thinking about this plan?</li> </ul>	<ul style="list-style-type: none"> <li>Must be thinking of actual method of suicide.</li> <li>Intent to carry out the plan is <u>not</u> required; formulation of a specific plan is enough.</li> <li>Include even if fleeting plan.</li> <li>Need <u>not</u> have been recurrent or feasible.</li> </ul>	<b>A. Rating Scale:</b> <table border="1"> <tr> <td><b>1</b> (Absent)</td> <td><b>2</b> (Sub-threshold)</td> <td><b>3</b> (Present)</td> </tr> </table>		<b>1</b> (Absent)	<b>2</b> (Sub-threshold)	<b>3</b> (Present)
		<b>1</b> (Absent)	<b>2</b> (Sub-threshold)	<b>3</b> (Present)		
		<b>B. ____</b> 1=Prior to the past 6 months 2=In the past 6 months				



CTP - Site ID _ _ _ _ . _ _ _ _	Participant ID _ _ _ _ _	Assessment Date: _ _ / _ _ / _ _ _ _ m m d d y y y y
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#### 4. Suicide gesture

<p>• Did you start to do something in order to kill yourself, even if you changed your mind and stopped, or if someone else stopped you? What did you do? What happened then? What were you thinking of when you did that?</p> <p>• <b>IF YES:</b> When was that? How many times did this happen?</p> <p><b>QSTESTCD/QSTEST</b></p>	<p>• Must be thinking about suicide at time of act but believe that the extent of action taken would not actually result in death</p> <p>• Include apparent suicide gesture even if subject claims intent was only attention-seeking</p> <p>• Exclude self-mutilation for tension-relief</p> <p>• Exclude preparation for attempt</p>	<p><b>A. Rating Scale:</b></p> <table border="1"> <tr> <td><b>1</b> (Absent)</td> <td><b>2</b> (Sub-threshold)</td> <td><b>3</b> (Present)</td> </tr> </table> <p><b>B. ____</b></p> <p>1=Prior to the past 6 months</p> <p>2=In the past 6 months</p> <p><b>QSORRES</b> <b>QSEVLINT</b></p>	<b>1</b> (Absent)	<b>2</b> (Sub-threshold)	<b>3</b> (Present)
<b>1</b> (Absent)	<b>2</b> (Sub-threshold)	<b>3</b> (Present)			

## 5. Suicide attempt

<p>• Did you ever do anything to hurt or kill yourself? Did you do anything on purpose that you knew could have killed you? (What did you do? What happened then? Did you think you could die as a result?)</p> <p>• <b>IF YES:</b> When was that? How many times did you do anything to kill yourself?</p>		<p>• Need not to have been planned or premeditated; include totally impulsive attempts</p> <p>• Very impulsive suicide behavior can occur even when other death/suicide items are negative</p> <p>• Include if completed act was believed to be lethal but subject was discovered and saved</p> <p>• Must have believed that act was lethal, regardless of objective lethality</p>		<p><b>A. Rating Scale:</b></p> <table border="1"> <tr> <td><b>1</b> (Absent)</td><td><b>3</b> (Present)</td></tr> </table> <p><b>B. ____</b></p> <p>1=Prior to the past 6 months</p> <p>2=In the past 6 months</p>		<b>1</b> (Absent)	<b>3</b> (Present)
<b>1</b> (Absent)	<b>3</b> (Present)						

## HOMICIDALITY

**6. Recurrent homicidal ideation:**

<ul style="list-style-type: none"> <li>Did you ever think about harming or killing someone? (What did you think of? How often did you have that thought?)</li> <li><b>IF YES:</b> Do you still think about harming or killing someone at the present time? How often? For how long have you been having these thoughts?</li> </ul>	<ul style="list-style-type: none"> <li>Must think actively of harming or killing someone, even if ambivalent.</li> <li>Can have homicidal ideation without having homicidal plan.</li> </ul>	<p><b>A. Rating Scale:</b></p> <table border="1"> <tr> <td><b>1</b> (Absent)</td> <td><b>2</b> (Sub-threshold)</td> <td><b>3</b> (Present)</td> </tr> </table> <p><b>B. _____</b></p> <p>1=Prior to the past 6 months</p> <p>2=In the past 6 months</p>	<b>1</b> (Absent)	<b>2</b> (Sub-threshold)	<b>3</b> (Present)
<b>1</b> (Absent)	<b>2</b> (Sub-threshold)	<b>3</b> (Present)			

(If Homicidal Ideation in past 6 months, above, ask question 7.)

## 7. Specific homicide plan

<ul style="list-style-type: none"> <li>Have you taken any steps toward carrying out this plan?</li> <li><b>IF YES:</b> What have you done?</li> </ul>	<ul style="list-style-type: none"> <li>Must be thinking of actual method of harming or killing someone.</li> <li>Intent to carry out the plan is <u>not</u> required; formulation of a specific plan is enough.</li> <li>Include even if fleeting plan.</li> <li>Need <u>not</u> have been recurrent or feasible.</li> </ul>	<b>A. Rating Scale:</b>	
		<b>1</b> (Absent)	<b>3</b> (Present)

**MINI MENTAL STATUS EXAM (MMSE) =QSCAT**
**STUDYID**
**DOMAIN: QS**

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<b>NODE:</b> ____		<b>STUDY Visit:</b> (circle one)	<b>EPOCH</b> Screening	<b>VISITNUM</b>
<b>CTP-SITE ID:</b> ____ - ____				
<b>PARTICIPANT ID:</b> ____	<b>USUBJID</b>			
<b>Assessment Date:</b> ____ / ____ / ____		<b>QSDTC</b> (mm / dd / yyyy)	<b>STAFF ID:</b> ____ <b>QSEVAL</b>	
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(Research Assistant/Independent Assessor Completed)

**For each question, check the correct responses, then enter the total score at left**
**QSTESTCD/QSTEST**
**QSORRES**
**Maximum Score:**

- \_\_\_\_ 1. What is the: [5]  
     \_\_\_\_ Year?  
     \_\_\_\_ Season?  
     \_\_\_\_ Date?  
     \_\_\_\_ Day?  
     \_\_\_\_ Month?
- \_\_\_\_ 2. Where are we: [5]  
     \_\_\_\_ State?  
     \_\_\_\_ County?  
     \_\_\_\_ Town?  
     \_\_\_\_ Street?  
     \_\_\_\_ Number?
- \_\_\_\_ 3. Name 3 objects: [3]  
     \_\_\_\_ Orange  
     \_\_\_\_ Airplane  
     \_\_\_\_ Tobacco
- \_\_\_\_ 4. Count backwards by 7's, starting at 100: [5]  
     \_\_\_\_ 93  
     \_\_\_\_ 86  
     \_\_\_\_ 79  
     \_\_\_\_ 72  
     \_\_\_\_ 65
- OR: spell WORLD backwards:
- \_\_\_\_ (D)  
     \_\_\_\_ (L)  
     \_\_\_\_ (R)  
     \_\_\_\_ (O)  
     \_\_\_\_ (W)
- \_\_\_\_ 5. Recall 3 objects: [3]  
     \_\_\_\_ Orange  
     \_\_\_\_ Airplane  
     \_\_\_\_ Tobacco
- \_\_\_\_ 6. Name a: [2]  
     \_\_\_\_ Pencil  
     \_\_\_\_ Watch
- \_\_\_\_ 7. Repeat the following: [1]  
     \_\_\_\_ "No ifs, ands, or buts."
- \_\_\_\_ 8. Follow a 3 stage command: [3]  
     \_\_\_\_ A. Take a paper in your right hand.  
     \_\_\_\_ B. Fold it in half.  
     \_\_\_\_ C. Put it on the floor.

For the following three items hand pages 2-4 to the participant, and ask her to follow the directions. Record the results below.

- \_\_\_\_ 9. Reading and obeying provided item [1]  
 \_\_\_\_ 10. Copying provided design [1]  
 \_\_\_\_ 11. Writing sample [1]

**\_\_\_\_ HAND MMSE Score (sum scores from questions 1 thru 11)** [30]

MMSE =QSCAT

CTP - Site ID ____ - ____	Participant ID <b>USUBJID</b> ____	Assessment Date: <b>QSDTC</b> ____ / ____ / ____ m m d d y y y y
------------------------------	--	--

**PARTICIPANT SECTION***Hand to participant to complete this section.***QSTESTCD/QSTEST****QSORRES**

(9) Read and obey:

**“Close Your Eyes”**

MMSE =QSCAT

PAGE 3 OF 4

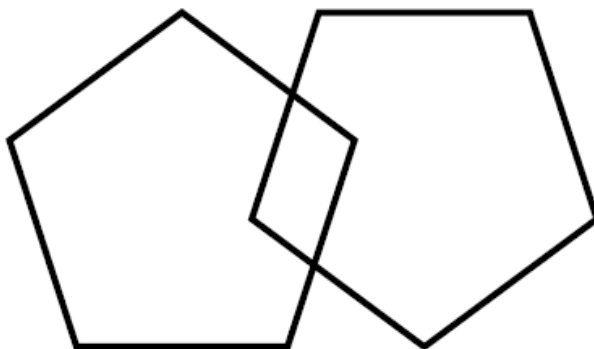
CTP - Site ID ____ - ____	Participant ID <b>USUBJID</b> ____	Assessment Date: ____ / <b>QSDTC</b> / ____ m m d d y y y y
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**PARTICIPANT SECTION**  
*Hand to participant to complete this section.*

(10) Copy the design of the intersecting pentagons (BELOW).

**QSTESTCD/QSTEST**

**QSORRES**



MMSE =QSCAT

PAGE 4 OF 4

CTP - Site ID ____ - ____	Participant ID <b>USUBJID</b> ____	Assessment Date: ____ / <b>QSDTC</b> / ____ m m d d y y y y
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**PARTICIPANT SECTION***Hand to participant to complete this section.*

(11) Write a sentence:

**QSTESTCD/QSTEST****QSORRES**

## PRIOR AND CONCOMITANT MEDICATIONS (PCM)

PAGE 1 OF 2

NIDA-CTN-0015		Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial		Seq. Num.: ____	
NODE: ____		STUDY Visit: (circle one)	EPOCH VISITNUM Screening Baseline		
CTP-SITE ID: ____ - ____			1-Wk FUP 3-Month FUP 6-Month FUP		
PARTICIPANT ID: ____ USUBJID			12-Month FUP		
Assessment Date: ____ / ____ / ____ (mm / dd / yyyy)			STAFF ID: ____		
FORM COMPLETION STATUS		1=CRF Administered 2=Participant refused 3=Staff Member did not Administer 4=Not enough time to Administer 5=No Participant Contact 6=Other			

(Research Assistant/Independent Assessor Completed)

Complete one CRF for each prescription medication the participant is taking for emotional, psychological, or psychiatric purposes. If a previously recorded medication's dose has changed, complete a new CRF for the medication and the new dosage.

Since your last visit\*...

- Have there been any dosage changes for prescription medications you are currently taking for emotional, psychological, or psychiatric purposes?
- Have you discontinued any of the prescription medications for emotional, psychological, or psychiatric purposes?
- Have you started any new prescription medications for emotional, psychological, or psychiatric purposes?

\*For the Screening visit assess the past 30 days. For the 1-Week Follow-Up, assess all prescription medications taken during Treatment Phase (study weeks 1 thru 6). For all other visits, assess period since last visit.

1.	New med or changed med 0=No (End questionnaire) 1=Yes (Continue with questions 2 thru 11)	Note: data only converted if PCM001 = 1
2.	Medication number	
3.	Report type 1=New medication (not previously recorded) (Skip to question 5) 2=Change in dose of a previously recorded medication (Complete question 4)	
4.	Medication number of previously recorded medication	
5.	Medication name (Generic name if possible; otherwise brand name):	
6.	Purpose/Indication (Reason drug is being taken): 1=Anti-depressants 2=Anti-anxiety 3=Anti-psychotic 4=Mood stabilizers 5=Sleep aids 6=Other (specify: _____)	QNAM=CMREPTYP QLABEL=MEDICATION REPORT TYPE IDVAR=CMSEQ
7.	Dosage quantity (i.e., 1200)	QNAM=CMMDSTAT QLABEL=MEDICATION STATUS IDVAR=CMSEQ
8.	Dosage units (Use units codes on the next page)	
9.	Current status of medication 1=Continuing (Participant still taking med) 2=Discontinued (Participant no longer taking med – complete question 11)	
10.	Start date (Date started or dose changed) ____ / ____ / ____ (mm/dd/yyyy)	
11.	Stop date (Date discontinued or changed) ____ / ____ / ____ (mm/dd/yyyy)	





## CAPS DIAGNOSIS SUMMARY (CAPS) =QSCAT STUDYID

PAGE 1 OF 2

<b>NIDA-CTN-0015</b>		<b>Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial</b>		<b>Seq. Num.: ____</b>	
<b>NODE:</b> ____	<b>STUDY Visit:</b> (circle one)		<b>EPOCH</b> Screening		<b>VISITNUM</b>
<b>CTP-SITE ID:</b> ____ - ____			1-Wk FUP	3-Month FUP	
<b>PARTICIPANT ID:</b> <b>USUBJID</b>			6-Month FUP	12-Month FUP	
<b>Assessment Date:</b> ____ <b>QSDTC</b> / ____ (mm / dd / yyyy)			<b>STAFF ID:</b> <b>QSEVAL</b>		
<b>FORM COMPLETION STATUS</b>			1=CRF Administered 2=Participant refused 3=Staff Member did not Administer 4=Not enough time to Administer 5=No Participant Contact 6=Other		

(Independent Assessor Completed)

**A. TRAUMATIC EVENT(s)**
 QNAM=QSINT, IDVAR=QSSEQ  
 QLABEL=SYMPTOM INTENSITY

(1) Traumatic event(s) or worst traumatic event(s) (Describe briefly. Record up to 3 events, 200 chars. max):

 QNAM=QSFREQ, IDVAR=QSSEQ  
 QLABEL=SYMPTOM FREQUENCY

QSORRES

**B. REEXPERIENCING SYMPTOMS**

QSTESTCD/QSTEST

	Frequency (a)					Intensity (b)					Present* (c) No Yes	
(1) Intrusive recollections	0	1	2	3	4	0	1	2	3	4	0	1
(2) Distressing dreams	0	1	2	3	4	0	1	2	3	4	0	1
(3) Acting or feeling as if event were recurring	0	1	2	3	4	0	1	2	3	4	0	1
(4) Psychological distress at exposure to cues	0	1	2	3	4	0	1	2	3	4	0	1
(5) Physiological reactivity on exposure to cues	0	1	2	3	4	0	1	2	3	4	0	1

\*(Symptom present if Frequency  $\geq 1$  and Intensity  $\geq 2$ )

(6) Number of Criterion B symptoms (need 1):

QNAM=QSCRTIB, IDVAR=QSGRPID, QLABEL= NUMBER OF CRITERION B SYMPTOMS

**C. AVOIDANCE AND NUMBING SYMPTOMS**

	Frequency (a)					Intensity (b)					Present* (c) No Yes	
(1) Avoidance of thoughts, feelings, or conversations	0	1	2	3	4	0	1	2	3	4	0	1
(2) Avoidance of activities, places, or people	0	1	2	3	4	0	1	2	3	4	0	1
(3) Inability to recall important aspect of trauma	0	1	2	3	4	0	1	2	3	4	0	1
(4) Diminished interest or participation in activities	0	1	2	3	4	0	1	2	3	4	0	1
(5) Detachment or estrangement	0	1	2	3	4	0	1	2	3	4	0	1
(6) Restricted range of affect	0	1	2	3	4	0	1	2	3	4	0	1
(7) Sense of a foreshortened future	0	1	2	3	4	0	1	2	3	4	0	1

\*(Symptom present if Frequency  $\geq 1$  and Intensity  $\geq 2$ )

(8) Number of Criterion C symptoms (need 3):

QNAM=QSCRTIC, IDVAR=QSGRPID, QLABEL= NUMBER OF CRITERION C SYMPTOMS

## CAPS DIAGNOSIS SUMMARY (CAPS) =QSCAT

QNAME=QSINT, IDVAR=QSSEQ  
QLABEL=SYMPTOM INTENSITY

PAGE 2 OF 2

CTP - Site ID _____	Participant ID <b>USUBJID</b>	Assessment Date: ____/____/____ m m / d d / y y y y
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QNAME=QSFREQ, IDVAR=QSSEQ  
QLABEL=SYMPTOM FREQUENCY

QSORRES

## D. HYPERAROUSAL SYMPTOMS

QSTESTCD/QSTEST

	Frequency (a)					Intensity (b)					Present* (c) No Yes	
(1) Difficulty falling or staying asleep	0	1	2	3	4	0	1	2	3	4	0	1
(2) Irritability or outbursts of anger	0	1	2	3	4	0	1	2	3	4	0	1
(3) Difficulty concentrating	0	1	2	3	4	0	1	2	3	4	0	1
(4) Hypervigilance	0	1	2	3	4	0	1	2	3	4	0	1
(5) Exaggerated startle response	0	1	2	3	4	0	1	2	3	4	0	1

\*(Symptom present if Frequency  $\geq 1$  and Intensity  $\geq 2$ )

(6) Number of Criterion D symptoms (need 2)

QSTESTCD/QSTEST

QNAME=QSCRITD  
IDVAR=QSGRPID,  
QLABEL= NUMBER OF  
CRITERION D SYMPTOMS

QSORRES

## E. DURATION OF DISTURBANCE

	NO	YES
(1) Duration of disturbance at least one month	0	1
(2) At what age did you first start having these symptoms you've told me about? ____		

QSTESTCD/QSTEST

QSORRES

## F. SIGNIFICANT DISTRESS OR IMPAIRMENT IN FUNCTIONING

	Intensity				
(1) Subjective distress	0	1	2	3	4
(2) Impairment in social functioning	0	1	2	3	4
(3) Impairment in occupational functioning	0	1	2	3	4
	NO		YES		
(4) AT LEAST ONE $\geq 2$ ?	0		1		

QSTESTCD/QSTEST

QSORRES

## G. PTSD DIAGNOSIS

(1) Diagnosis (select one) ____ 1 = Full PTSD – All Criteria (A-F) are met 2 = Subthreshold PTSD – Criteria A, B, E, F, plus either C or D are met 3 = No Full or Subthreshold PTSD
--

# INCLUSION – EXCLUSION CHECKLIST (IEC)

PAGE 1 OF 1

<b>NIDA-CTN-0015</b>	<b>Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial</b>		<b>Seq. Num.: ____</b>
<b>NODE:</b> ____	<b>STUDY Visit:</b> (circle one)	<b>EPOCH</b> <b>VISITNUM</b> Screening	
<b>CTP-SITE ID:</b> ____ - ____			
<b>PARTICIPANT ID:</b> <u>USUBJID</u>			
<b>Assessment Date:</b> ____ / ____ / ____ (mm / dd / yyyy)		<b>STAFF ID:</b> ____	
<b>FORM COMPLETION STATUS</b>		1-CRF Administered 2-Participant refused 3-Staff Member did not Administer 4-Not enough time to Administer 5-No Participant Contact 6-Other	

(Research Assistant/Independent Assessor Completed)

1. INCLUSION CRITERIA			IECAT	TEST
YES	NO	UNK		
1	0	-9	1a.	Participant is female, and between 18 and 65 years old.
1	0	-9	1b.	Participant has used an illicit substance within the past six months and has current diagnosis of illicit drug abuse or dependence (with or without alcohol) or has used alcohol within the past 6 months and has current diagnosis of alcohol abuse or dependence.
1	0	-9	1c.	Participant is diagnosed as having either: a. Full PTSD (meets criteria A, B, C, D, E, F). b. Subthreshold PTSD (meets criteria A, B, E, F, plus either C or D).
1	0	-9	1d.	Participant has given informed consent.
1	0	-9	1e.	Participant is enrolled in treatment at the CTP.

If any of the inclusion questions above have been answered NO or UNKNOWN then the participant is not eligible and cannot be entered or randomized into the study. Please continue to question 2a.

2. EXCLUSION CRITERIA				
YES	NO	UNK		
1	0	-9	2a.	Participant has an advanced stage medical disease (i.e. AIDS, TB) as indicated by global physical deterioration and incapacitation.
1	0	-9	2b.	Participant has an impaired mental status (MMSE score is less than 22).
1	0	-9	2c.	Participant has significant risk of suicidal intent, behavior or history.
1	0	-9	2d.	Participant has current homicidal intent or plan.
1	0	-9	2e.	Participant has history of a schizophrenio-spectrum diagnosis.
1	0	-9	2f.	Participant has a history of active (past two months) psychosis.
1	0	-9	2g.	Participant is involved in litigation concerning PTSD.
1	0	-9	2h.	Participant refuses to be audio-taped or video-taped.

If any of the Exclusion questions above are answered YES or UNKNOWN, the participant is not eligible and cannot be entered or randomized into the study. Please continue to question 3a.

3. ELIGIBILITY			SC.SCORRES	TEST
YES	NO	UNK		
1	0	-9	3a.	Is the participant eligible for the study? if no or unknown, skip to 3c.
			3b.	Date of eligibility: ____ / ____ / ____ (mm / dd / yyyy)
			3c.	Specify ineligibility: _____

<b>NIDA-CTN-0015</b>		Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial		Seq. Num.: ____	
NODE: ____		STUDY Visit: (circle one)	EPOCH Baseline VISITNUM		
CTP-SITE ID: ____ - ____					
PARTICIPANT ID: ____	USUBJID				
Assessment Date: ____ / ____ / ____		QSDTC	(mm / dd / yyyy)	STAFF ID: ____	QSEVAL
FORM COMPLETION STATUS		1=CRF Administered 2=Participant refused 3=Staff Member did not Administer 4=Not enough time to Administer 5=No Participant Contact 6=Other			

(Independent Assessor Completed)

Participant Date of Birth (mm/dd/yyyy): \_\_\_\_ / \_\_\_\_ / \_\_\_\_

**Composite Scores**  
(for site use only):

Medical: ____	Legal: ____
Employment: ____	Family: ____
Drug: ____	Psychiatric: ____
Alcohol: ____	

**KEY:**

Patient Rating Scale
0 = Not at all
1 = Slightly
2 = Moderately
3 = Considerably
4 = Extremely

Introducing the ASI
<p>Seven potential problem areas: Medical, Employment/Support Status, Alcohol, Drug, Legal, Family/Social, and Psychological. All clients receive this same <u>standard</u> interview. All information gathered is <u>confidential</u>.</p> <p>There are <u>two time periods</u> we will discuss:</p> <ol style="list-style-type: none"> <li>1. The past 30 days</li> <li>2. Lifetime Data</li> </ol> <p><b>Patient Rating Scale:</b> Patient input is important. For each area, I will ask you to use this scale to let me know how bothered you have been by any problems in each section. I will also ask you how important treatment is for you for the area being discussed.</p> <p>Please refer to the Patient Rating Scale in the adjacent key.</p> <p>If you are uncomfortable giving an answer, then don't answer. <i>Please do not give inaccurate information!</i></p>

Interviewer Instructions
<ol style="list-style-type: none"> <li>1. Leave no blanks.</li> <li>2. Make plenty of Comments (if another person reads this ASI, they should have a relatively complete picture of the client's perceptions of his/her problems).</li> <li>3. Throughout the ASI, when noted: <b>X</b> = Question not answered. <b>N</b> = Question not applicable.</li> <li>4. Terminate interview if client misrepresents two or more sections.</li> <li>5. When noting comments, please write the question number.</li> </ol> <p><b>HALF TIME RULE:</b> If a question asks the number of months, round up periods of 14 days or more to 1 month. Round up 6 months or more to 1 year.</p> <p><b>CONFIDENCE RATINGS:</b></p> <ul style="list-style-type: none"> <li>⇒ Last two items in each section.</li> <li>⇒ Do not over interpret.</li> <li>⇒ Denial does not warrant misrepresentation.</li> <li>⇒ Misrepresentation = overt contradiction in information.</li> </ul> <p><i>Probe and make plenty of comments!</i></p>



CTP - Site ID ____-____	Participant ID <b>USUBJID</b>	Assessment Date: ____ / <b>QSDTC</b> / ____ m m d d y y y y
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## GENERAL INFORMATION

=QSSCAT

QSORRES

## QSTEST

Q30

G9. Contact code:  
1-In person  
2-Telephone (Intake ASI must be in person)  
3-Mail  
X=Not Answered

---

G12. Special:  
1-Patient terminated  
2-Patient refused  
3-Patient unable to respond  
N=Not Applicable

QSORRESU=YEAR / QSORRESU=MONTH

         /           
a. Yrs.      b. Mos.

G14. How long have you lived at your current address?  
(XX/XX=Not Answered)

G18. Do you have a religious preference?

1=Protestant	5=Other (specify _____)
2=Catholic	6=None
3=Jewish	X=Not Answered
4=Islamic	

QSEVLINT=-P30D

---

G19. Have you been in a controlled environment in the past 30 days? A place, theoretically, without access to drugs/alcohol.

1=No	5=Psychiatric Treatment
2=Jail	6=Other (specify _____)
3=Alcohol or Drug Treatment	X=Not Answered
4=Medical Treatment	

---

G20. How many days? "NN" if question G19 is "No". Refers to total number of days detained in the past 30 days. (XX=Not Answered)

QSEVLINT=-P30D QSORRESU=DAY

Comments:

**Data not entered**

CTP - Site ID ____ - ____	Participant ID <b>USUBJID</b>	Assessment Date: ____ / ____ / ____ <b>QSDTC</b> m m d d y y y y
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**MEDICAL STATUS** =QSSCAT

QSTEST

**QSORRES** M1. How many times in your life have you been hospitalized for medical problems?

Include O.D.'s, D.T.'s. Exclude detox, alcohol/drug, and psychiatric treatment and childbirth (if no complications). Enter the number of overnight hospitalizations for medical problems. (X=Not Answered)

\_\_\_\_ M3. Do you have any chronic medical problems which continue to interfere with your life?

0=No, 1=Yes

A chronic medical condition is a serious physical or medical condition that requires regular care, (i.e., medication, dietary restriction) preventing full advantage of their abilities. (X=Not Answered)

If "Yes," specify: \_\_\_\_\_

\_\_\_\_ M4. Are you taking any prescribed medication on a regular basis for a physical problem?

0=No, 1=Yes

Medication prescribed by a MD for medical conditions; not psychiatric medicines. Include medicines prescribed whether or not the patient is currently taking them. The intent is to verify chronic medical problems. (X=Not Answered)

If "Yes," specify: \_\_\_\_\_

\_\_\_\_ M5. Do you receive a pension for a physical disability? (X= Not Answered)

0=No, 1=Yes

Include Workers' compensation, exclude psychiatric disability.

If "Yes," specify: \_\_\_\_\_

\_\_\_\_ M6. How many days have you experienced medical problems in the past 30 days?

Do not include ailments directly caused by drugs/alcohol. Include flu, colds, etc. Include serious ailments related to drugs/alcohol, which would continue even if the patient were abstinent (e.g., cirrhosis of liver, abscesses from needles, etc.). (X=Not Answered)

**QSORRESU=DAY QSEVLINT=P30D**  
For Questions M7 & M8, please ask the patient to use the Patient Rating scale.

\_\_\_\_ M7. How troubled or bothered have you been by these medical problems in the past 30 days?

Restrict response to problem days of Question M6. (X=Not Answered)

\_\_\_\_ M8. How important to you now is treatment for these medical problems?

Refers to the need for new or additional medical treatment by the patient. (X=Not Answered)

**CONFIDENCE RATINGS**

Is the above information significantly distorted by:

\_\_\_\_ M10. Patient's misrepresentation?

0=No, 1=Yes

\_\_\_\_ M11. Patient's inability to understand?

0=No, 1=Yes

Comments:

Data not entered



CTP - Site ID _____-_____-_____-	Participant ID <u>USUBJID</u>	Assessment Date: ____/____/____ m m d d y y y y
-------------------------------------	----------------------------------	--

**EMPLOYMENT/SUPPORT STATUS =QSSCAT**

QSORRESU=YEAR / QSORRESU=MONTH

\_\_\_\_\_/\_\_\_\_\_  
a. Yrs. / b. Mos.

E1. Education completed?

QSTEST

GED = 12 years. Include formal education only. (XX/XX=Not Answered)

QSORRESU=MONTH

Mos.

QSORRES

E2. Training or technical education completed:

Formal/organized training only. For military training, only include training that can be used in civilian life (i.e., electronics or computers). (XX=Not Answered)

0=No, 1=Yes

E4. Do you have a valid driver's license? Valid license; not suspended/revoked. (X=Not Answered)

0=No, 1=Yes

E5. Do you have an automobile available? (If answer to E4 is "No", then E5 must be "No")

Does not require ownership, only requires availability on a regular basis. (X=Not Answered)

QSORRESU=YEAR / QSORRESU=MONTH

\_\_\_\_\_/\_\_\_\_\_  
a. Yrs. / b. Mos.

E6. How long was your longest full time job?

Full time = 35+ hours weekly; does not necessarily mean most recent job. (XX/XX=Not Answered)

E7. Usual (or last) occupation? (specify): \_\_\_\_\_  
(use Hollingshead Categories Reference Sheet) (X=Not Answered)

0=No, 1=Yes

E9. Does someone contribute the majority of your support?  
Is patient receiving any regular support (i.e., cash, food, housing) from family/friend? Include spouse's contribution; exclude support by an institution. (X=Not Answered, N=Not Applicable)

QSEVLINT=-P3Y

E10. Usual employment pattern, past three years?

- |                                  |                               |
|----------------------------------|-------------------------------|
| 1 = Full time (35+ hrs/wk)       | 6 = Retired/Disability        |
| 2 = Part time (regular hours)    | 7 = Unemployed                |
| 3 = Part time (Irreg., day work) | 8 = In controlled environment |
| 4 = Student                      | (X=Not Answered)              |
| 5 = Military Service             |                               |

Answer should represent the majority of the last 3 years, not just the most recent selection. If there are equal times for more than one category, select that which best represents the more current situation.

QSORRESU=DAY

QSEVLINT=-P30D

\_\_\_\_\_-\_\_\_\_\_-\_\_\_\_\_-

E11. How many days were you paid for working in the past 30 days?

Include "under the table" work, paid sick days, and vacation. (XX=Not Answered)

Max=\$99999

**For questions E12-E17: How much money did you receive from the following sources in the past 30 days?**

\$ \_\_\_\_\_

E12. Employment (net income)? (Net or "take home" pay, include any "under the table" money.) (XXXXX=Not Answered)

\$ \_\_\_\_\_

E13. Unemployment Compensation? (XXXXX=Not Answered)

\$ \_\_\_\_\_

E14. Welfare? (Include food stamps, transportation money provided by an agency to go to and from treatment.) (XXXXX=Not Answered)

\$ \_\_\_\_\_

E15. Pensions, benefits or Social Security? (Include disability, pensions, retirement, veteran's benefits, SSI &amp; workers' compensation.) (XXXXX=Not Answered)

Comments:

Data not entered

QSEVLINT=-P30D  
QSORRESU=DOLLAR

CTP - Site ID _____	Participant ID <u>USUBJID</u>	Assessment Date: ____ / ____ / ____ <u>QSDTC</u> m m d d y y y y
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\$        **QSORRES**E16. **QSTEST**

Mate, family or friends? (Money for personal expenses, (i.e., clothing), include unreliable sources of income (e.g., gambling). Record cash payments only. Include windfalls (unexpected), money from loans, gambling, inheritance, tax returns, etc.). (XXXXX=Not Answered)

\$       

E17. Illegal? (XXXXX=Not Answered)

Cash obtained from drug dealing, stealing, fencing stolen goods, gambling, prostitution, etc. Do Not attempt to convert drugs exchanged to a dollar value.

               
Max = 99

E18. How many people depend on you for the majority of their food, shelter, etc.?

Must be regularly depending on patient, do include alimony/child support, do not include the patient or self-supporting spouse, etc. (XX=Not Answered)

E19. How many days have you experienced employment problems in the past 30 days?

Include inability to find work, if they are actively looking for work, or problems with present job in which that job is jeopardized. (XX=Not Answered)

**QSEVLINT=-P30D QSORRESU=DAY**

**For Questions E20 & E21, ask the patient to use the Patient Rating scale.**

**QSEVLINT=-P30D**

The patient's ratings in Questions E20 & E21 refer to Question E19. Stress help in finding or preparing for a job, not giving them a job.

**Data not entered**      

E20. How troubled or bothered have you been by these employment problems in the past 30 days?

If the patient has been incarcerated or detained during the past 30 days, they cannot have employment problems. (X=Not Answered)

      E21. How important to you now, is counseling for these employment problems? (X=Not Answered)**CONFIDENCE RATINGS**

Is the above information significantly distorted by:

        
0=No, 1=Yes

E23. Patient's misrepresentation?

        
0=No, 1=Yes

E24. Patient's inability to understand?



CTP - Site ID _____	Participant ID <u>USUBJID</u>	Assessment Date: ____/____/____ m m d d y y y y
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QSTEST

How many times in your life have you been treated for: Include detoxification, halfway houses, inpatient counseling, and AA or NA (if 3+ meetings within one month period). (XX=Not Answered)

Comments:

QSORRES

D19. Alcohol abuse?

D20. Drug abuse?

How many of these were detox only?

D21. Alcohol? If D19 = "00", then question D21 is "NN" (XX=Not Answered)

D22. Drugs? If D20 = "00", then question D22 is "NN" (XX=Not Answered)

How much money would you say you spent during the past 30 days on: Only count actual money spent. What is the financial burden caused by drugs/alcohol? (XXXXX=Not Answered)

Max = \$99999

\$ \_\_\_\_\_

D23. Alcohol? QSEVLINT=-P30D QSORRESU=DOLLAR

\$ \_\_\_\_\_

D24. Drugs? QSEVLINT=-P30D QSORRESU=DOLLAR

D25. How many days have you been treated in an outpatient setting for alcohol or drugs in the past 30 days? (Include AA/NA) (XX=Not Answered)

QSEVLINT=-P30D QSORRESU=DAY

For questions D28 - D31, please ask the patient to use the Patient Rating scale.

The Patient is rating the need for additional substance abuse treatment. (X=Not Answered)

How many days in the past 30 have you experienced:

D26. Alcohol problems? QSEVLINT=-P30D QSORRESU=DAY

How troubled or bothered have you been in the past 30 days by these:

D28. Alcohol problems? QSEVLINT=-P30D QSORRESU=DAY

How important to you now is treatment for these:

D30. Alcohol problems?

How many days in the past 30 have you experienced:

D27. Drug problems?

Include: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to. (XX=Not Answered)

How troubled or bothered have you been in the past 30 days by these:

QSEVLINT=-P30D

D29. Drug problems?

QSEVLINT=-P30D

How important to you now is treatment for these:

D31. Drug problems?

CONFIDENCE RATINGS

Is the above information significantly distorted by:

0=No, 1=Yes

D34. Patient's misrepresentation?

0=No, 1=Yes

D35. Patient's inability to understand?

Data not entered

## ASL

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CTP - Site ID ____ - ____	Participant ID <u>USUBJID</u>	Assessment Date: ____ / ____ / ____ QSDTC m m d d y y y y
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**LEGAL STATUS** =QSSCAT  
 QSTEST

QSORRES

0=No, 1=Yes

L1. Was this admission prompted by the criminal justice system?

Judge, probation/parole officer, etc. (X=Not Answered)

L2. Are you on parole or probation?

0=No, 1=Yes

Note duration and level in comments. (X=Not Answered)

**How many times in your life have you been arrested and charged with the following:**

Include total number of counts, not just convictions. Do not include juvenile (pre-age 18) crimes, unless they were charged as an adult. Include formal charges only. (XX=Not Answered)

- |                                      |                                  |
|--------------------------------------|----------------------------------|
| ____ L3. Shoplifting/Vandalism       | ____ L10. Assault                |
| ____ L4. Parole/Probation Violations | ____ L11. Arson                  |
| ____ L5. Drug Charges                | ____ L12. Rape                   |
| ____ L6. Forgery                     | ____ L13. Homicide/Manslaughter  |
| ____ L7. Weapons Offense             | ____ L14. Prostitution           |
| ____ L8. Burglary/Larceny/B&E        | ____ L15. Contempt of court      |
| ____ L9. Robbery                     | ____ L16. Other: (specify _____) |

L17. How many of these charges resulted in convictions? If L3-L16="00", then L17="NN". Do not include misdemeanor offenses from questions L18-L20 below. Convictions include fines, probation, incarcerations, suspended sentences, and guilty pleas. (XX=Not Answered)

**How many times in your life have you been charged with the following:**

\_\_\_\_ L18. Disorderly conduct, vagrancy, public intoxication? (XX=Not Answered)

\_\_\_\_ L19. Driving while intoxicated (DWI)? (XX=Not Answered)

\_\_\_\_ L20. Major driving violations?  
Moving violations: speeding, reckless driving, no license, etc. (XX=Not Answered)

\_\_\_\_ L21. How many months were you incarcerated in your life? if incarcerated 2 weeks or more, round this up to 1 month. List total number of months incarcerated (up to 99). If more than 99, code 99 and enter the number in comments. (XX=Not Answered)

\_\_\_\_ L24. Are you presently awaiting charges, trial, or sentence? (X=Not Answered)

0=No, 1=Yes

Comments:

Data not entered

QSORRESU=MONTH

CTP - Site ID ____ - ____	Participant ID ____ <b>USUBJID</b> ____	Assessment Date: ____ / ____ / <b>QSDTC</b> ____ m ____ m ____ d ____ d ____ y ____ y ____ y ____ y
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QSORRES

QSTEST

\_\_\_\_

L25. What for? (Refers to L24.) Use code 03-16, 18-20. If more than one, choose most severe.

Don't include civil cases, unless a criminal offense is involved. (XX=Not Answered, NN= Not Applicable)

03 = Shoplifting

12 = Rape

04 = Probation violation

13 = Homicide

05 = Drug

14 = Prostitution

06 = Forgery

15 = Contempt

07 = Weapons

16 = Other

08 = Burglary

18 = Disorderly conduct

09 = Robbery

19 = DWI

10 = Assault

20 = Major driving violation

11 = Arson

\_\_\_\_

L26. How many days in the past 30, were you detained or incarcerated?

QSEVLINT=-P30D QSORRESU=DAY

Include being arrested and released on the same day. (XX=Not Answered)

\_\_\_\_

L27. How many days in the past 30, have you engaged in illegal activities for profit?

QSEVLINT=-P30D QSORRESU=DAY

Exclude simple drug possession. Include drug dealing, prostitution, selling stolen goods, etc. May be cross-checked with Question E17 under Employment/Family Support Section. (XX=Not Answered)

For questions L28 & L29, ask the patient to use the Patient Rating scale.

\_\_\_\_

L28. How serious do you feel your present legal problems are?  
Exclude civil problems. (X=Not Answered)

\_\_\_\_

L29. How important to you now is counseling or referral for these legal problems?

Patient is rating a need for additional referral to legal counsel for defense against criminal charges. (X=Not Answered)

#### CONFIDENCE RATINGS

Is the above information significantly distorted by:

\_\_\_\_

L31. Patient's misrepresentation?

0=No, 1=Yes

\_\_\_\_

L32. Patient's inability to understand?

0=No, 1=Yes

Comments:

Data not entered

CTP - Site ID _____	Participant ID <u>USUBJID</u>	Assessment Date: ____/____/____ <u>QSDTC</u> m m d d y y y y
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**FAMILY/SOCIAL RELATIONSHIPS**

=QSSCAT

QSORRESF1. Marital Status QSTEST

- 1 = Married    3 = Widowed    5 = Divorced  
 2 = Remarried    4 = Separated    6 = Never Married  
 Common-law marriage = "1." (Specify in comments) (X=Not Answered)

0=No, 1=Indifferent,  
2=Yes

F3. Are you satisfied with this situation? (Refers to Question F1)  
 Satisfied = generally liking the situation. (X=Not Answered)

QSEVLINT=-P3Y

F4. Usual living arrangements (past 3 years):

- 1 = With sexual partner & children    6 = With friends  
 2 = With sexual partner alone    7 = Alone  
 3 = With children alone    8 = Controlled Environment  
 4 = With parents    9 = No stable arrangement  
 5 = With family

Choose arrangements most representative of the past 3 years. If there is an even split in time between these arrangements, choose the most recent arrangement. (X=Not Answered)

0=No, 1=Indifferent,  
2=Yes

F6. Are you satisfied with these arrangements?  
 Refers to response in Question F4. (X=Not Answered)

Do you live with anyone who:

Comments:

0=No, 1=Yes

F7. Has a current alcohol problem? (X=Not Answered)

0=No, 1=Yes

F8. Uses non-prescribed drugs? (X=Not Answered)

1=Family,  
2=Friends, 3=Alone

F9. With whom do you spend most of your free time?

If a girlfriend/boyfriend is considered as a family by patient, then they must refer to them as family throughout this section, not a friend. Family is not to be referred to as "friend." (X=Not Answered)

0=No, 1=Indifferent,  
2=Yes

F10. Are you satisfied with spending your free time this way?  
 (Refers to Question F9.)  
 A satisfied response must indicate that the person generally likes the situation. (X=Not Answered)

Have you had significant periods in which you have experienced serious problems getting along with: "Serious problems" mean those that endangered the relationship. A "problem" requires contact of some sort, either by telephone or in person.

a. Past 30 Days    b. Life-time

0= No, 1= Yes, (X= Not Answered, N= Not Applicable)

- |       |       |   |
|-------|-------|---|
| _____ | _____ | F18. Mother                                   |
| _____ | _____ | F19. Father                                   |
| _____ | _____ | F20. Brothers/Sisters                         |
| _____ | _____ | F21. Sexual Partner/Spouse                    |
| _____ | _____ | F22. Children                                 |
| _____ | _____ | F23. Other Significant Family (Specify _____) |
| _____ | _____ | F24. Close Friends                            |
| _____ | _____ | F25. Neighbors                                |
| _____ | _____ | F26. Co-workers                               |

Data not entered

QSEVLINT=-P30D





CTP - Site ID _____	Participant ID _____	Assessment Date: ____ / ____ / ____ QSDTC m m d d y y y y
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**PSYCHIATRIC STATUS=QSSCAT****QSTEST**

**How many times have you been treated for any psychological or emotional problems:**

Do not include substance abuse, employment, or family counseling. Treatment episode = a series of more or less continuous visits or treatment days, not the number of visits or treatment days. Enter diagnosis in comments if known.

**QSORRES**

\_\_\_\_\_

P1. In a Hospital or inpatient setting? (XX= Not Answered)

\_\_\_\_\_

P2. Outpatient/private patient? (XX= Not Answered)

0=No, 1=Yes

P3. Do you receive a pension for a psychiatric disability? (X=Not Answered)

**Have you had a significant period of time (that was not a direct result of alcohol/drug use) in which you have:**

a. Past 30 Days    b. Life-time

0=No, 1=Yes, (X= Not Answered)

**QSEVLINT=-P30D**

P4. Experienced serious depression-sadness, hopelessness, loss of interest, difficulty with daily function?

P5. Experienced serious anxiety/tension-uptight, unreasonably worried, inability to feel relaxed?

P6. Experienced hallucinations-saw things or heard voices that other people did not see or hear?

P7. Experienced trouble understanding, concentrating, or remembering?

For questions P8-P10, patient could have been under the influence of alcohol/drugs.

P8. Experienced trouble controlling violent behavior including episodes of rage, or violence? (Patient can be under the influence of alcohol/drugs.)

P9. Experienced serious thoughts of suicide? Patient seriously considered a plan for taking his/her life.

P10. Attempted suicide? (Include actual suicidal gestures or attempts.)

P11. Been prescribed medication for any psychological or emotional problems? (Prescribed for the patient by MD. Record "Yes" if a medication was prescribed even if the patient is not taking it.)

P12. How many days in the past 30 have you experienced these psychological or emotional problems? (This refers to problems noted in Questions P4-P10.) (XX= Not Answered)

Comments:

Data not entered

**QSEVLINT=-P30D QSORRESU=DAY**

CTP - Site ID _____ - _____	Participant ID <u>USUBJID</u>	Assessment Date: ____ / ____ / ____ m m d d y y y y
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For Question P13 & P14, ask the patient to use the Patient

Rating scale.

QSTEST

Comments:

QSORRES

QSEVLINT=-P30D

P13. How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days? (Patient should be rating the problem days from Question P12.) (X= Not Answered)

P14. How important to you now is treatment for these psychological or emotional problems? (X= Not Answered)

#### CONFIDENCE RATING

Is the above information significantly distorted by:

P22. Patient's misrepresentation?

0=No, 1=Yes

P23. Patient's inability to understand?

0=No, 1=Yes

Data not entered

## ADDENDUM TO ASI-LITE (ADD)

QSCAT=ASI ADDENDUM FOR WOMEN

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<b>NIDA-CTN-0015</b>	<b>Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial</b>		<b>Seq. Num.: ____</b>
<b>NODE:</b> ____	<b>STUDY Visit:</b> (circle one)	<b>EPOCH VISITNUM</b>	<b>Baseline</b>
<b>CTP-SITE ID:</b> ____ - ____			
<b>PARTICIPANT ID:</b> <u>USUBJID</u>			
<b>Assessment Date:</b> ____ / ____ / ____ <b>QSDTC</b> (mm / dd / yyyy)		<b>STAFF ID:</b> <u>QSEVAL</u>	
<b>FORM COMPLETION STATUS</b>	1=CRF Administered 2=Participant refused 3=Staff Member did not Administer 4=Not enough time to Administer 5=No Participant Contact 6=Other		

(Independent Assessor Completed)

A. When did you first enroll in a treatment program at this clinic? \_\_\_\_ / \_\_\_\_ / \_\_\_\_ (mm/dd/yyyy)

Yes	No	NA	Recruitment/Screening Sources	
				<b>Are you currently under pressure to come to or stay in treatment from the following sources?</b>
				<b>QSTEST</b>
			1a.	An employer, school, or training program
			1b.	Your lawyer
			1c.	A court, parole, or probation officer, or other part of the criminal justice system
			1d.	A housing or other community agency
			1e.	Your church or close friend
			1f.	Your spouse, partner, or family
			1g.	Department of Children and Family Services (Child Protection Services agency)
			1h.	Other source (If yes, specify below in question 1i.)
			1i.	Other source (specify): _____
Yes	No	NA	Reproductive Health Questions	
			2.	When you first started having your period, how old were you?
			3.	Have you ever been pregnant? (If no or not answered, skip to question 13a. If yes, continue with question 4.)
			4.	How old were you when you became pregnant for the first time?
			5.	How old were you when you became pregnant for the last time/most recent time?
			6.	How many times have you been pregnant?
			7a.	Were any babies born alive but later died? (If yes, ask question 7b. If no or not answered, skip to question 8a.)
			7b.	If yes, how many?
			8a.	Have you had any abortions? (If yes, ask question 8b. If no or not answered, skip to question 9a.)
			8b.	If yes, how many?
			9a.	Have you had any miscarriages? (If yes, ask question 9b. If no or not answered, skip to question 10a.)
			9b.	If yes, how many?
			10a.	Did you ever have a stillbirth? (If yes, ask question 10b. If no or not answered, skip to question 11a.)
			10b.	If yes, how many?
			11a.	Were any babies born prematurely and survived? (If yes, ask question 11b. If no or not answered, skip to question 12a.)

ADD

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CTP - Site ID ____ - ____	Participant ID <b>USUBJID</b>	Assessment Date: ____ / ____ / ____ <b>QSDTC</b> m m d d y y y y
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Yes	No	NA	Reproductive Health Questions (continued)	
<b>QSORRES</b>			11b.	If yes, how many? <b>QSTEST</b>
1	0	-9	12a.	Did you use any drugs during <u>any</u> pregnancies (does not include prescribed medication, e.g., methadone)? <i>(If yes, ask question 12b. If no or not answered, skip to question 13a.)</i>
			12b.	Was it during all of the pregnancies <u>or</u> some of the pregnancies? 1 = All 2 = Some of the pregnancies
1	0	-9	13a.	Have you gone through menopause (or already experienced the change of life)? <i>(If no or not answered, ask question 13b. If yes, skip to question 14a.)</i>
1	0	-9	13b.	If no, are you currently in menopause?
Yes	No	NA	Legal	
				Do you have any legal problems involving your family (i.e., the members of your household), such as...?
1	0	-9	14a.	Family or juvenile court?
1	0	-9	14b.	Child custody involving DHS?
1	0	-9	14c.	Divorce?
1	0	-9	14d.	Domestic violence?
1	0	-9	14e.	Department of immigration?
1	0	-9	14f.	Other <i>(If yes, specify below in question 14g.)</i>
			14g.	Other (specify): _____
Yes	No	NA	Family/Social	
1	0	-9	15.	Have you ever been homeless or not had a permanent place to live?
1	0	-9	16a.	Do you have any children living with you? <i>(If yes, ask questions 16b thru 17p. If no or not answered, skip to question 18a.)</i>
			16b.	Have your children usually been living with you in the past three years? 1 = Yes, all 2 = Yes, some 3 = No, none <b>QSEVLINT=-P3Y</b>
			16c.	How many children live in your household?
			16d.	How many of those are your biological children?
				Is there anyone who helps you on a regular basis to take care of your children who are living with you (e.g., babysitting, preparing meals, feeding kids, bathing, dressing children)? <i>(Circle yes or no for each item.)</i>
1	0	-9	17a.	Child's biological mother?
1	0	-9	17b.	Child's biological father?
1	0	-9	17c.	Child's stepmother?
1	0	-9	17d.	Child's stepfather?
1	0	-9	17e.	Foster mother?
1	0	-9	17f.	Foster father?
1	0	-9	17g.	Child's brother/sister?
1	0	-9	17h.	Client's sex partner/spouse?
1	0	-9	17i.	Child's grandmother?
1	0	-9	17j.	Child's grandfather?

ADD

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CTP - Site ID ____ - ____	Participant ID <b>USUBJID</b>	Assessment Date: ____ / ____ / <b>QSDTC</b> m m d d y y y y
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Yes	No	NA		Family/Social (continued)
1	0	-9	17k.	Client's GM/GF? <b>QSTEST</b>
1	0	-9	17l.	Other significant family?
1	0	-9	17m.	Close friends?
1	0	-9	17n.	Neighbors?
1	0	-9	17o.	Other clients?
1	0	-9	17p.	Other? (If yes, specify below in question 17q.)
			17q.	Other (specify): _____

Yes	No	NA		
1	0	-9	18a.	As an adult, over the age of 18, has anyone used physical violence (such as being slapped, pushed, hit or punched) or the threat of physical violence against you? (If yes, ask questions 18b-18f. If no or not answered, skip to question 19a.)
				If yes, how was this person related to you:
1	0	-9	18b.	Spouse ?
1	0	-9	18c.	Other family member?
1	0	-9	18d.	Partner/significant other?
1	0	-9	18e.	Stranger?
1	0	-9	18f.	Did you receive medical treatment for any injuries as a result of physical violence against you?

Yes	No	NA		
1	0	-9	19a.	As an adult, has anyone used sexual violence (forcing you to do anything sexual) or the threat of sexual violence against you? (If yes, ask questions 19b-19f. If no or not answered, skip to question 20a.)
				If yes, how was this person related to you:
1	0	-9	19b.	Spouse?
1	0	-9	19c.	Other family member?
1	0	-9	19d.	Partner/significant other?
1	0	-9	19e.	Stranger?
1	0	-9	19f.	Did you receive medical treatment for any injuries as a result of sexual violence against you?

Yes	No	NA		
1	0	-9	20a.	When you were a child (under the age of 18), did anyone ever use physical violence (like doing something on purpose that gave you bruises, broke bones or made you bleed) or the threat of violence against you? (If yes, ask questions 20b-20f. If no or not answered, skip to question 21a.)
				If yes, how was this person related to you:
1	0	-9	20b.	Parent?
1	0	-9	20c.	Other family member?
1	0	-9	20d.	Partner/significant other?
1	0	-9	20e.	Stranger?

CTP - Site ID ____ - ____	Participant ID <b>USUBJID</b>	Assessment Date: ____ / ____ / <b>QSDTC</b> m m d d y y y y
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Yes	No	NA	<b>QSTEST</b>	
1	0	-9	20f.	Did you receive medical treatment for any injuries as a result of physical violence against you?
<b>QSORRES</b>				
Yes	No	NA		
1	0	-9	21a.	When you were a child (under the age of 18), were you ever the victim of sexual abuse or sexual assault or engaged in any sexual activity against your will, like someone touching you sexually or making you do sexual things that you did not want, etc? (If yes, ask questions 21b-21f. If no or not answered, skip to question 22.)
				If yes, how was this person related to you:
1	0	-9	21b.	Parent?
1	0	-9	21c.	Other family member?
1	0	-9	21d.	Partner/significant other?
1	0	-9	21e.	Stranger?
1	0	-9	21f.	Did you receive medical treatment for any injuries as a result of sexual violence against you?
			<b>Overall Health</b>	
		___	22.	Please rate your current health status in general: 1 = Excellent 2 = Good 3 = Fair 4 = Poor 5 = Very poor -9 = Not answered
			<b>Please tell me how much you agree or disagree with the following statements:</b>	
		___	23.	I am somewhat ill. 1 = Strongly agree 2 = Somewhat agree 3 = Neither agree nor disagree 4 = Somewhat disagree 5 = Strongly disagree -9 = Not answered
		___	24.	I am as healthy as anybody I know. 1 = Strongly agree 2 = Somewhat agree 3 = Neither agree nor disagree 4 = Somewhat disagree 5 = Strongly disagree -9 = Not answered
		___	25.	My health is excellent. 1 = Strongly agree 2 = Somewhat agree 3 = Neither agree nor disagree 4 = Somewhat disagree 5 = Strongly disagree -9 = Not answered
		___	26.	I have been feeling bad lately. 1 = Strongly agree 2 = Somewhat agree 3 = Neither agree nor disagree 4 = Somewhat disagree 5 = Strongly disagree -9 = Not answered



# RISK BEHAVIOR SURVEY (RBS)

QSCAT=RISK BEHAVIORS SURVEY

DOMAIN: QS

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NIDA-CTN-0015		STUDYID		Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial		Seq. Num.: _____	
CODE:	_____	USUBJID	_____	STUDY Visit: (circle one)		EPOCH	
CTP-SITE ID:	_____	_____		1 Wk-FUP	3-Month FUP	6-Month FUP	12-Month FUP
PARTICIPANT ID:	_____	_____		STAFF ID:		QSEVAL	
Assessment Date: _____ / _____		QSDTC		(mm / dd / yyyy)		_____	
FORM COMPLETION STATUS		1-CRF Administered 2-Participant refused 3-Staff Member did not Administer		4-Not enough time to Administer 5-No Participant Contact 6-Other		_____	

(Independent Assessor Completed)

INTERVIEWER: The RBS contains sensitive information on drug use and sexual behavior. Please ensure that you have developed rapport with the participant before asking these questions.

QSCAT = DRUG USE QSEVLINT=P3OD

A. DRUG USE

QSTEST	a.			b.	c.	d.	e.	f.
	Have you ever used? (if no use, skip to next drug)	How many days did you use _____ in the last 30 days? (if 00, do not ask parts c-f, and skip to next drug)	How many days did you inject _____ in the last 30 days? (if 00, skip to part e)					
1.	NO	YES	UNK	REF	QSORRESU=DAY	QSORRESU=DAY	QSORRESU=DAY	QSORRESU=DAY
Cocaine by itself (injected or snorted)	0	1	9	7	_____	_____	_____	_____
Heroin by itself	0	1	9	7	_____	_____	_____	_____
Heroin & Cocaine mixed together (Speedball)	0	1	9	7	_____	_____	_____	_____
Other Opiates (Demerol, Codeine, Dilaudid)	0	1	9	7	_____	_____	_____	_____
Amphetamines (Speed, Methamphetamine, Crank)	0	1	9	7	_____	_____	_____	_____

CTP - Site ID _____ - _____	Participant ID <u>USUBJID</u>	Assessment Date: ____ / ____ / <u>QSDTC</u> m m d d y y y y
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## B. DRUG INJECTION *(if no injection use in past 30 days, skip to Section C)*

QSTEST

QSEVLINT=-P30D

- \_\_\_\_\_ 1. In the last 30 days, how many times (# of injections) did you inject using works (needle/syringes) that you know had been used by somebody else? *(If 000, then skip to B3)*
- \_\_\_\_\_ 2. Of the times you injected after someone, how many times did you clean the works with full-strength bleach? *(Number cannot exceed total number of times used after a friend (qB1).)*
- \_\_\_\_\_ 3. How many times in the last 30 days did you use a cooker/cotton/rinse water that had been used by another injector?
- \_\_\_\_\_ 4. How many times in the last 30 days did you fix drugs with another person, then split the drug solution (through use of the same cooker/spoon or through front or back loading)?

## C. SEXUAL ACTIVITY

QSSCAT=SEXUAL ACTIVITY

Now I'm going to ask you some questions about sex. I'm referring here to anybody you've had sex with in the last 30 days.

- \_\_\_\_\_ 1. During the last 30 days, with how many people did you have vaginal, oral or anal sex?

*(IF NONE, ENTER 000 AND THE QUESTIONNAIRE IS COMPLETED)*

- \_\_\_\_\_ 2. How many of your partners were female? *(Number cannot exceed total number of people (qC1))*
- \_\_\_\_\_ 3. How many of your partners were male? *(Number cannot exceed total number of people (qC1))*

*Please use the following coding for frequency of sexual events and condom/barrier use.*

Frequency scale:		Condom/Barrier use scale:	
Once or irregularly	01	Never	0
Less than once a week	02	Less than half the time	1
About once a week	03	About half the time	2
2-6 times a week	04	More than half the time	3
About once a day	05	Always	4
2-3 times a day	06	Don't know/unsure	9
4 or more times a day	07	Refused	7
Don't know/unsure	99		
Refused	77		

- \_\_\_\_\_ 4. Interviewer: Code gender of respondent (1=Male, 2=Female, 9=Don't Know)

*(If Male, complete sections D, E, F, G & I)*

*(If Female, complete sections D, G, H, & I)*

*(If Don't Know, ask ALL sex/gender specific questions and allow client to answer as they like.)*

## D. Ask Male/Female Clients who had Female Partners

QSSCAT=SEXUAL ACTIVITY - CLIENT WITH FEMALE PARTNER

- \_\_\_\_\_ 1.a How many women performed oral sex ("went down") on you?  
*(If 000, then skip to question 2a. Number cannot exceed total number of female partners (qC2))*
- \_\_\_\_\_ 1.b How often did your partner(s) perform oral sex ("go down") on you? *(Use frequency scale)*
- \_\_\_\_\_ 1.c How often did you use condoms/dental dams when your partner(s) perform oral sex ("went down") on you? *(Use condom/barrier use scale)*
- \_\_\_\_\_ 2.a How many women did you perform oral sex ("go down") on?  
*(If 000, then skip to next section appropriate for the sex of this client. Number cannot exceed total number of female partners (qC2))*
- \_\_\_\_\_ 2.b How often did you perform oral sex ("go down") on your partner(s)? *(Use frequency scale)*
- \_\_\_\_\_ 2.c How often did you use condoms/dental dams when you performed oral sex ("went down") on your partner(s)? *(Use condom/barrier use scale)*

CTP - Site ID ____ - ____	Participant ID <u>USUBJID</u>	Assessment Date: ____ / ____ / ____ m m d d y y y y
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<b>Frequency scale:</b>		<b>Condom/Barrier use scale:</b>	
Once or irregularly	01	Never	0
Less than once a week	02	Less than half the time	1
About once a week	03	About half the time	2
2-6 times a week	04	More than half the time	3
About once a day	05	Always	4
2-3 times a day	06	Don't know/unsure	9
4 or more times a day	07	Refused	7
Don't know/unsure	99		
Refused	77		

QSSCAT=SEXUAL ACTIVITY – MALE CLIENT WITH FEMALE PARTNER

QSEVLINT=-P30D

**E. Ask Male Clients who had Female Partners:**

- \_\_\_\_ 1.a How many women did you have vaginal sex with? **QSTEST**  
(If 000, then skip to question 2a. Number cannot exceed total number of female partners (qC2))
- QSORRES** \_\_\_\_ 1.b How often did you have vaginal sex? (Use frequency scale)
- \_\_\_\_ 1.c How often did you use a condom? (Use condom/barrier use scale)
- \_\_\_\_ 2.a How many women did you have (insertive) anal sex with?  
(If 000, then skip to next section appropriate for the sex of this client. Number cannot exceed total number of female partners (qC2))
- \_\_\_\_ 2.b How often did you have (insertive) anal sex? (Use frequency scale)
- \_\_\_\_ 2.c How often did you use a condom? (Use condom/barrier use scale)

**F. Ask Male Clients who had Male Partners:**

QSSCAT=SEXUAL ACTIVITY

- MALE CLIENT WITH MALE PARTNER

- \_\_\_\_ 1.a How many men did you have (insertive) anal sex with?  
(If 000, then skip to next section appropriate for the sex of this client. Number cannot exceed total number of male partners (qC3))
- \_\_\_\_ 1.b How often did you have (insertive) anal sex? (Use frequency scale)
- \_\_\_\_ 1.c How often did you use a condom? (Use condom/barrier use scale)

**G. Ask Male/Female Clients who had Male Partners**

QSSCAT=SEXUAL ACTIVITY

- CLIENT WITH MALE PARTNER

- \_\_\_\_ 1.a How many men performed oral sex ("went down") on you?  
(If 000, then skip to question 2a. Number cannot exceed total number of male partners (qC3))
- \_\_\_\_ 1.b How often did your partner(s) perform oral sex ("go down") on you? (Use frequency scale)
- \_\_\_\_ 1.c How often did you use condoms/dental dams when your partner(s) perform oral sex ("went down") on you? (Use condom/barrier use scale)
- \_\_\_\_ 2.a How many men did you perform oral sex ("go down") on?  
(If 000, then skip to next section appropriate for the sex of this client. Number cannot exceed total number of male partners (qC3))
- \_\_\_\_ 2.b How often did you perform oral sex ("go down") on your partner(s)? (Use frequency scale)
- \_\_\_\_ 2.c How often did you use condoms/dental dams when you performed oral sex ("went down") on your partner(s)? (Use condom/barrier use scale)

**H. Ask Female Clients who had Male Partners:**

QSSCAT=SEXUAL ACTIVITY

FEMALE CLIENT WITH MALE PARTNER

- \_\_\_\_ 1.a How many men did you have vaginal sex with?  
(If 000, then skip to next section appropriate for the sex of this client. Number cannot exceed total number of male partners (qC3))
- \_\_\_\_ 1.b How often did you have vaginal sex? (Use frequency scale)
- \_\_\_\_ 1.c How often did you use a condom? (Use condom/barrier use scale)

**I. Ask Male/Female Clients who had Male Partners**

QSSCAT=SEXUAL ACTIVITY

CLIENT WITH MALE PARTNER

- \_\_\_\_ 1.a How many men did you have (receptive) anal sex with?  
(If 000, end questionnaire. Number cannot exceed total number of male partners (qC3))
- \_\_\_\_ 1.b How often did you have (receptive) anal sex? (Use frequency scale)
- \_\_\_\_ 1.c How often did you use a condom? (Use condom/barrier use scale)

## NON-STUDY MEDICAL SERVICES - FOLLOW-UP (NSMF)

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<b>NIDA-CTN-0015</b>	<b>Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial</b>			<b>Seq. Num.:</b> ____
<b>NODE:</b> ____	<b>STUDY Visit:</b> (circle one)	<div>3-Month FUP</div> <div>6-Month FUP</div> <div>12-Month FUP</div> <div><b>EPOCH</b></div> <div><b>VISITNUM</b></div>		
<b>CTP-SITE ID:</b> ____ - ____				
<b>PARTICIPANT ID:</b> <u>USUBJID</u>				
<b>Assessment Date:</b> ____ / ____ / ____ <b>TUDTC</b> (mm / dd / yyyy)		<b>STAFF ID:</b> ____		
<b>FORM COMPLETION STATUS</b>	1=CRF Administered 2=Participant refused 3=Staff Member did not Administer 4=Not enough time to Administer 5=No Participant Contact 6=Other			

(Independent Assessor Completed)

TUTEST/ TUTESTCD

A. When did the participant last complete this form? \_\_\_\_ / \_\_\_\_ / \_\_\_\_ **TUORRES** (mm/dd/yyyy)

We'd like you to answer these questions for the medical services you've received including those that are part of this outpatient program (but excluding those associated with this study).

Yes	No	In the past 30 days, have you...		<b>TUEVLINT=-P30D</b>
1	0	1a.	Seen a therapist, that is a psychiatrist, psychologist, counselor, or social worker for drug, psychological, or emotional problems? (If no or not answered, then skip to question 2a, below)	<b>TUTEST/ TUTESTCD</b>
<b>TUORRES</b>		1b.	____ (If YES), how many times did you see a psychiatrist or psychologist?	
		1c.	____ (If YES), how many times did you see a counselor or social worker?	
1	0	2a.	Visited a medical office, not including your therapist? (Include all visits to a physician, nurse, or nurse practitioner, or physician's assistant) (If no or not answered, then skip to question 3a, below)	
		2b.	____ (If YES), how many visits to a medical office have you had?	
		2c.	____ (If YES), how many of these visits did you see a doctor?	
1	0	3a.	Been admitted into a residential program to detoxify or for other services? (If no or not answered, then skip to question 4a, below)	
		3b.	____ (If YES), how many admissions?	
		3c.	____ (If YES), how many nights for all stays?	
1	0	4a.	Been admitted into a hospital to detoxify? (If no or not answered, then skip to question 5a, below)	
		4b.	____ (If YES), how many admissions?	
		4c.	____ (If YES), how many nights for all stays?	
1	0	5a.	Been admitted to the hospital for any other reason? (If no or not answered, then skip to question 6a, below)	
		5b.	____ (If YES), how many times were you admitted?	
		5c.	____ (If at least once), how many nights for all stays?	
1	0	6a.	Visited an emergency room and not been admitted to the hospital? (If no or not answered, then skip to question 7a, below)	
		6b.	____ (If YES), how many times did you visit the emergency room?	
1	0	7a.	Attended any 12-step or self – help meetings? (If no or not answered, then end interview)	
		7b.	____ (If YES), how many times did you attend 12-step or self – help meetings?	

<b>NIDA-CTN-0015</b>		<b>Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial</b>		<b>Seq. Num.: ____</b>	
<b>NODE:</b> ____		<b>STUDY Visit:</b> (circle one)	Baseline		
<b>CTP-SITE ID:</b> ____ - ____			1-Wk FUP      3-Month FUP		
<b>PARTICIPANT ID:</b> ____ <b>USUBJID</b>			6-Month FUP      12-Month FUP		
<b>Assessment Date:</b> ____ / ____ / ____ <b>QSDTC</b> (mm / dd / yyyy)			<b>STAFF ID:</b> ____ <b>QSEVAL</b>		
<b>FORM COMPLETION STATUS</b>		1=CRF Administered 2=Participant refused 3=Staff Member did not Administer 4=Not enough time to Administer 5=No Participant Contact 6=Other			

(Independent Assessor Completed)

INSTRUCTIONS: On the next page is a list of problems people sometimes have. Please read each one carefully, and circle the number that best describes HOW MUCH THAT PROBLEM HAS DISTRESSED OR BOTHERED YOU DURING THE PAST 7 DAYS INCLUDING TODAY. Circle only one number for each problem and do not skip any items. If you change your mind, cross out the incorrect circle with an 'X' and circle the correct response. Read the example before beginning, and if you have any questions please ask them now.

EXAMPLE						
QSTEST		Not at all	A little bit	Moderately	Quite a bit	Extremely
#	How much were you distressed by:					
1	Bodyaches	0	1	2	③	4

QSORRES



BSI =QSCAT

CTP - Site ID _____ - _____	Participant ID _____ <b>USUBJID</b> _____	Assessment Date: ____ / ____ / ____ <b>QSDTC</b> m m / d d / y y y y
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#	<b>QSTEST</b> How much were you distressed by:	<b>QSORRES</b>				
		Not at all	A little bit	Moderately	Quite a bit	Extremely
1	Nervousness or shakiness inside	0	1	2	3	4
2	Faintness or dizziness	0	1	2	3	4
3	The idea that someone else can control your thoughts	0	1	2	3	4
4	Feeling others are to blame for most of your troubles	0	1	2	3	4
5	Trouble remembering things	0	1	2	3	4
6	Feeling easily annoyed or irritated	0	1	2	3	4
7	Pains in heart or chest	0	1	2	3	4
8	Feeling afraid in open spaces or on the streets	0	1	2	3	4
9	Thoughts of ending your life	0	1	2	3	4
10	Feeling that most people cannot be trusted	0	1	2	3	4
11	Poor appetite	0	1	2	3	4
12	Being suddenly scared for no reason	0	1	2	3	4
13	Temper outbursts that you could not control	0	1	2	3	4
14	Feeling lonely even when you are with people	0	1	2	3	4
15	Feeling blocked in getting things done	0	1	2	3	4
16	Feeling lonely	0	1	2	3	4
17	Feeling blue	0	1	2	3	4
18	Feeling no interest in things	0	1	2	3	4
19	Feeling fearful	0	1	2	3	4
20	Your feelings being easily hurt	0	1	2	3	4
21	Feeling that people are unfriendly or dislike you	0	1	2	3	4
22	Feeling inferior to others	0	1	2	3	4
23	Nausea or upset stomach	0	1	2	3	4
24	Feeling that you are watched or talked about by others	0	1	2	3	4
25	Trouble falling asleep	0	1	2	3	4
26	Having to check and double-check what you do	0	1	2	3	4
27	Difficulty making decisions	0	1	2	3	4
28	Feeling afraid to travel on buses, subways, or trains	0	1	2	3	4
29	Trouble getting your breath	0	1	2	3	4
30	Hot or cold spells	0	1	2	3	4
31	Having to avoid certain things, places, or activities because they frighten you	0	1	2	3	4
32	Your mind going blank	0	1	2	3	4
33	Numbness or tingling in parts of your body	0	1	2	3	4

QSEVLINT=-P7D

CTP - Site ID _____	Participant ID <u>USUBJID</u>	Assessment Date: ____ / ____ / ____	QSDTC ____
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#	QSTEST How much were you distressed by:	QSORRES				
		Not at all	A little bit	Moderately	Quite a bit	Extremely
34	The idea that you should be punished for your sins	0	1	2	3	4
35	Feeling hopeless about the future	0	1	2	3	4
36	Trouble concentrating	0	1	2	3	4
37	Feeling weak in parts of your body	0	1	2	3	4
38	Feeling tense or keyed up	0	1	2	3	4
39	Thoughts of death or dying	0	1	2	3	4
40	Having urges to beat, injure, or harm someone	0	1	2	3	4
41	Having urges to break or smash things	0	1	2	3	4
42	Feeling very self-conscious with others	0	1	2	3	4
43	Feeling uneasy in crowds, such as shopping or at a movie	0	1	2	3	4
44	Never feeling close to another person	0	1	2	3	4
45	Spells of terror or panic	0	1	2	3	4
46	Getting into frequent arguments	0	1	2	3	4
47	Feeling nervous when you are left alone	0	1	2	3	4
48	Others not giving you proper credit for your achievements	0	1	2	3	4
49	Feeling so restless you couldn't sit still	0	1	2	3	4
50	Feelings of worthlessness	0	1	2	3	4
51	Feeling that people will take advantage of you if you let them	0	1	2	3	4
52	Feelings of guilt	0	1	2	3	4
53	The idea that something is wrong with your mind	0	1	2	3	4

QSEVLINT=-P7D

STUDYID

## POST-TRAUMATIC SYMPTOM SELF REPORT (PSSR) =QSCAT

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<b>NIDA-CTN-0015</b>		<b>Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial</b>		<b>Seq. Num.: ____</b>		
<b>NODE:</b> ____		<b>STUDY Visit: (circle one)</b>	Baseline	Wk1v1	Wk1v2	
<b>CTP-SITE ID:</b> ____ - ____			Wk3v1	Wk3v2	Wk4v1	Wk4v2
<b>PARTICIPANT ID:</b> ____ <b>USUBJID</b>			Wk6v1	Wk6v2	1-Wk FUP	3-Month FUP
<b>Assessment Date:</b> ____ / ____ / ____ <b>QSDTC</b> (mm / dd / yyyy)		<b>EPOCH</b> 6-Month FUP		<b>12-Month FUP</b> <b>VISITNUM</b>		
<b>STAFF ID:</b> ____ <b>QSEVAL</b>						
<b>FORM COMPLETION STATUS</b>		1=CRF Administered 2=Participant refused 3=Staff Member did not Administer 4=Not enough time to Administer 5=No Participant Contact 6=Other				

(Research Assistant/Independent Assessor Completed)

## THESE QUESTIONS REFER TO YOUR TRAUMATIC EVENT(S).

This scale measures the frequency and severity of symptoms since your last visit.\* For each symptom, please indicate the **FREQUENCY** and **SEVERITY** by entering the appropriate code from the table below. If a symptom did not occur at all (Frequency=1) during the assessment period, then code the Severity as 'not at all' (code 1).

\*For the Baseline and Follow-Up assessments, the participant should consider her symptoms in the past 7 days. During the Treatment Phase of the study, she should consider the symptoms since her last visit.

FREQUENCY SCALE:	SEVERITY SCALE:
1=Not at all	1=Not at all
2=Once a week	2=A little bit
3=2-4 times per week/Half the time	3=Moderately
4=5 or more times per week/Almost always	4=Quite a bit
	5=Extremely

FOR BASELINE AND FOLLOWUP:  
QSEVLINT = -P7D FOR ALL VARIABLES

## QSTEST

		(a) FREQUENCY	(b) SEVERITY
1	Having upsetting thoughts or images about the trauma that came into your head when you didn't want them to.	____	____
2	Having bad dreams or nightmares about the trauma.	____	____
3	Reliving the trauma, acting or feeling as if it was happening again.	____	____
4	Feeling emotionally upset when you were reminded of the trauma (for example, feeling scared, angry, sad, guilty, etc.).	____	____
5	Trying not to think about, talk about, or have feelings about the trauma.	____	____
6	Trying to avoid activities, people, or places that remind you of the trauma.	____	____
7	Not being able to remember an important part of the trauma.	____	____
8	Having less much less interest or participating much less often in important activities.	____	____
9	Feeling distant or cut off from people around you.	____	____
10	Feeling emotionally numb (for example, being unable to cry or unable to have loving feelings).	____	____
11	Feeling as if future plans or hopes will not come true (for example, will have no career, marriage, children, or long life).	____	____
12	Having trouble falling or staying asleep.	____	____
13	Feeling irritable or having fits of anger.	____	____
14	Having trouble concentrating (for example, drifting in and out of conversations, losing track of a story on television, forgetting what you read).	____	____
15	Being over-alert (for example, checking to see who is around you, being uncomfortable with your back to the door, etc.).	____	____
16	Being jumpy or easily startled (for example, when someone walks up behind you).	____	____
17	Experiencing PHYSICAL reactions when you were reminded of the trauma (for example, breaking out in a sweat, heart beating fast).	____	____



<b>NIDA-CTN-0015</b>		<b>Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial</b>				<b>Seq. Num.: ____</b>		
<b>NODE:</b> ____		<b>STUDY Visit:</b> (circle one)	Baseline	Wk1v1	Wk1v2	Wk2v1	Wk2v2	
<b>CTP-SITE ID:</b> ____ - ____			Wk3v1	Wk3v2	Wk4v1	Wk4v2	Wk5v1	Wk5v2
<b>PARTICIPANT ID:</b> ____ <b>USUBJID</b>			Wk6v1	Wk6v2	1-Wk FUP	3-Month FUP		
<b>Assessment Date:</b> ____ / ____ / ____		<b>QSDTC</b> (mm / dd / yyyy)	<b>EPOCH</b>	<b>6-Month FUP</b>		<b>12-Month FUP</b>		
<b>STAFF ID:</b> ____		<b>QSEVAL</b>						
<b>FORM COMPLETION STATUS</b>		1=CRF Administered 2=Participant refused 3=Staff Member did not Administer 4=Not enough time to Administer 5=No Participant Contact 6=Other						

(Research Assistant/Independent Assessor Completed)

**QSTEST**

(RA/IA will complete Q1.)

**FOR BASELINE AND FOLLOWUP:**  
**QSEVLINT = -P7D FOR ALL VARIABLES**

 1. When did the participant last complete this form? \_\_\_\_ / \_\_\_\_ **QSORRES**  
 (mm/dd/yyyy)

(For baseline and follow-up assessments, leave question 1 blank and ask the participant to evaluate her substance use in the past 7 days. For treatment phase assessments, the participant should evaluate her substance use between the day before the current day, and the date of her last visit, indicated in question 1.)

**ALCOHOL USE****QSORRES****=QSSCAT**

2a. Number of days on which alcohol was used (If 0 or not answered, skip to Q.2g)

**QSORRESU=DAYS**2b. Average number of drinks per day

2c. Maximum dollar value of alcohol used in one day

**QSORRESU=DOLLARS**

(Answer Q.2d and Q.2e, even if there is no alcohol use at all.)

2d. Number of days on which urge, desire or craving for alcohol occurred

**QSORRESU=DAYS**

2e. How strong was the urge? How hard was it to resist?

0 = None

1 = Mild urges, easily resisted

2 = Moderate urges, requiring effort to resist

3 = Strong urges to use, difficult to resist

4 = Severe, usually impossible to resist urges to use

**COCAINE USE****=QSSCAT**

3a. Number of days on which cocaine was used (If 0 or not answered, skip to Q.3e)

**QSORRESU=DAYS**3b. Average dollar value of cocaine used per day**QSORRESU=DOLLARS**

3c. Maximum dollar value of cocaine used in one day

**QSORRESU=DOLLARS**

3d. Principal route of cocaine use:

1 = Oral

2 = Inhaled

3 = Smoked (freebase/crack)

4 = Non-I.V. injection

5 = I.V.

6 = Other

(Answer Q.3e and Q.3f, even if there is no cocaine use at all.)

3e. Number of days on which urge, desire or craving for cocaine occurred

**QSORRESU=DAYS**

CTP - Site ID ____-____-____	Participant ID <u>USUBJID</u>	Assessment Date: ____/____/____ m m d d y y y y	QSDTC
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## QSTEST

- \_\_\_\_ 3f. How strong was the urge? How hard was it to resist?
- 0 = None
  - 1 = Mild urges, easily resisted
  - 2 = Moderate urges, requiring effort to resist
  - 3 = Strong urges to use, difficult to resist
  - 4 = Severe, usually impossible to resist urges to use

## QSORRES

## HEROIN USE =QSSCAT

- \_\_\_\_ 4a. Number of days on which heroin was used (If 0 or not answered, skip to Q.4e) QSORRESU=DAYS
- \_\_\_\_ 4b. Average dollar value of heroin used per day QSORRESU=DOLLARS
- \_\_\_\_ 4c. Maximum dollar value of heroin used in one day QSORRESU=DOLLARS
- \_\_\_\_ 4d. Principal route of heroin use:
- 1 = Oral
  - 2 = Inhaled
  - 3 = Smoked (freebase)
  - 4 = Non-I.V. injection
  - 5 = I.V.
  - 6 = Other
- (Answer Q.4e and Q.4f, even if there is no heroin use at all.)
- \_\_\_\_ 4e. Number of days on which urge, desire or craving for heroin occurred QSORRESU=DAYS
- \_\_\_\_ 4f. How strong was the urge? How hard was it to resist?
- 0 = None
  - 1 = Mild urges, easily resisted
  - 2 = Moderate urges, requiring effort to resist
  - 3 = Strong urges to use, difficult to resist
  - 4 = Severe, usually impossible to resist urges to use

## MARIJUANA USE =QSSCAT

- \_\_\_\_ 5a. Number of days on which marijuana was used (If 0 or not answered, skip to Q.5e) QSORRESU=DAYS
- \_\_\_\_ 5b. Average dollar value of marijuana used per day QSORRESU=DOLLARS
- \_\_\_\_ 5c. Maximum dollar value of marijuana used in one day QSORRESU=DOLLARS
- \_\_\_\_ 5d. Principal route of marijuana use:
- 1 = Smoked
  - 2 = Oral
  - 3 = Other

CTP - Site ID _____	Participant ID <b>USUBJID</b> _____	Assessment Date: ____/____/____ <b>QSDTC</b> m m d d y y y y
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**QSTEST**  
(Answer Q.5e and Q.5f, even if there is no marijuana use at all.)

**QSORRES**

5e. Number of days on which urge, desire or craving for marijuana occurred **QSORRESU=DAYS**

5f. How strong was the urge? How hard was it to resist?  
 0 = None  
 1 = Mild urges, easily resisted  
 2 = Moderate urges, requiring effort to resist  
 3 = Strong urges to use, difficult to resist  
 4 = Severe, usually impossible to resist urges to use

Any Other Drug: Number of Days of Use of Each of the Following: **=QSSCAT**

6a. Other sedatives/hypnotics

6b. Stimulants

6c. PCP (angel dust)

6d. Hallucinogens

6e. Any other Drug (Specify drug in Q.6e1, below. If 0 or not answered, skip to Q.6f.)

6e1. Other drug used specified: \_\_\_\_\_ (maximum 200 characters)  
 (Answer Q.6f and Q.6g, even if there is no other drug use at all. When answering 6f and 6g, think about the substance in 6a thru 6e that was used most often.)

6f. Number of days on which urge, desire or craving for any other drug occurred **QSORRESU=DAYS**

6g. How strong was the urge? How hard was it to resist?  
 0 = None  
 1 = Mild urges, easily resisted  
 2 = Moderate urges, requiring effort to resist  
 3 = Strong urges to use, difficult to resist  
 4 = Severe, usually impossible to resist urges to use

Summary Drug Use: **=QSSCAT**

7a. Number of days using any illicit drugs or alcohol **QSORRESU=DAYS**

7b. Number of days using any IV or SC (subcutaneous injection) drugs **QSORRESU=DAYS**

7c. Number of days having the urge, desire or craving for any drug **QSORRESU=DAYS**

7d. How strong was the urge? How hard was it to resist?  
 0 = None  
 1 = Mild urges, easily resisted  
 2 = Moderate urges, requiring effort to resist  
 3 = Strong urges to use, difficult to resist  
 4 = Severe, usually impossible to resist urges to use

## ADVERSE EVENTS (AE)

STUDYID

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<b>NIDA-CTN-0015</b>		Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial		Seq. Num.: ____	
NODE: ____		STUDY Visit: (circle one)	Baseline Wk1v1 Wk1v2 Wk2v1 Wk2v2		
CTP-SITE ID: ____ - ____			Wk3v1 Wk3v2 Wk4v1 Wk4v2 Wk5v1 Wk5v2		
PARTICIPANT ID: ____ <b>USUBJID</b>			Wk6v1 Wk6v2 1-Wk FUP 3-Month FUP 6-Month FUP		
Assessment Date: ____ / ____ / ____ <b>AEDTC</b> (mm / dd / yyyy)		<b>EPOCH</b>		12-Month FUP <b>VISITNUM</b>	
____ FORM COMPLETION STATUS		1=CRF Administered 2=Participant refused 3=Staff Member did not Administer		4=Not enough time to Administer 5=No Participant Contact 6=Other	

(Research Assistant/Independent Assessor/MD, PhD, PI Completed)

AESPID

1. Did the participant have any new or changed AE since the last assessment?

0=No (End questionnaire)

1=Yes

IF NO, THEN NO RECORD EXISTS IN SDTM AE FILE

2. AE Number

AETERM (AEDECOD, AEBODSYS)

3. AE Term (Brief Description): \_\_\_\_\_

4a. Change in severity of previously reported AE?

0=No (Skip to question 5)

1=Yes

QNAM = AESEVCHG

QLABEL = AE SEVERITY CHANGE

IDVAR = AESEQ

4b. (If Yes) Previous AE Number: \_\_\_\_\_

5. Serious\*

0=No

1=Yes

AESER

6a. Onset Date \_\_\_\_ / \_\_\_\_ / \_\_\_\_ **AESTDTC** (mm/dd/yyyy)6b. Onset Time **AESTDTC** (hh:mm, 24-hour clock)

AESEV

7. Severity

1=Mild

2=Moderate

3=Severe

AEREL

8. Study Related?

0=No

1=Yes

AEACN

9. Action Taken

1=None

2=Stop Treatment

3=Other Medication

4=Medical Care

5=Hospitalization\*

AEOUT

10. Final Outcome

1=Resolved

2=Resolved with Sequelae

3=Not resolved (Skip questions 11a and 11b)

4=Death\*

11a. Final Outcome Date \_\_\_\_ / \_\_\_\_ / \_\_\_\_ **AEENDTC** (mm/dd/yyyy)11b. Final Outcome Time **AEENDTC** (hh:mm, 24-hour clock)

**AE**

PAGE 2 OF 2

CTP - Site ID ____ - ____	Participant ID ____ <b>USUBJID</b>	Assessment Date: ____ / ____ / <b>AEDTC</b> m m d d y y y y
------------------------------	---------------------------------------	--

12. Signature: \_\_\_\_\_ (MD, PhD, or PI)      Date signed: \_\_\_\_/\_\_\_\_/\_\_\_\_ **AESIGDT** (mm/dd/yyyy)

\* All Serious Adverse Events (SAE) must have a complete AE CRF, SAE Form, SAE Summary Report. Initial and date once these steps are completed.

- Report AE/SAEs in accordance with the study protocol and local IRB requirements
- SAEs must be reported within 24 hours (see SOM)

## URINE DRUG SCREEN (UDS)

LBCAT=DRUG SCREEN

STUDYID

PAGE 1 OF 1

<b>NIDA-CTN-0015</b>	<b>Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial</b>		<b>Seq. Num.:</b> ____
<b>NODE:</b> ____	<b>USUBJID</b>	Baseline Wk1v1 Wk1v2 Wk2v1 Wk2v2	
<b>CTP-SITE ID:</b> ____ - ____	<b>STUDY Visit:</b> (circle one)	Wk3v1 Wk3v2 Wk4v1 Wk4v2 Wk5v1 Wk5v2	
<b>PARTICIPANT ID:</b> ____		Wk6v1 Wk6v2 1-Wk FUP 3-Month FUP 6-Month FUP 12-Month FUP	
<b>Assessment Date:</b> ____ / ____ / ____ (mm / dd / yyyy)		<b>STAFF ID:</b> ____	
<b>FORM COMPLETION STATUS</b>	1=CRF Administered 2=Participant refused 3=Staff Member did not Administer 4=Not enough time to Administer 5=No Participant Contact 6=Other		

1. Was a Urine Drug Screen Performed? \_\_\_\_ (0=No, 1=Yes, 7=Lost Sample, 9=Unknown)

If 0 or 9, the questionnaire is completed. If 7, answer only questions 1 and 2 of this CRF.

2. Date urine collected (mm/dd/yyyy): \_\_\_\_ / \_\_\_\_ / \_\_\_\_ **LBDC**

3. Urine temperature within expected range? \_\_\_\_ (Temperature 92°F ≤ X ≤ 96°F OR ≥ 33.3°C)

0 = No  
1 = Yes  
9 = Unknown

**QNAME = LBTEMP**  
**QLABEL = URINE TEMP WITHIN EXPECTED RANGE**  
**IDVAR = LBSEQ**

4. Was this urine collection supervised?

0 = No  
1 = Yes  
9 = Unknown

**QNAME = LBSUPER**  
**QLABEL = URINE COLLECTION SUPERVISED**  
**IDVAR = LBSEQ**

**QNAME = LBVISDTC**  
**QLABEL = URINE**  
**COLLECTION VISIT DATE**  
**IDVAR = LBSEQ**

(Circle the number representing the result of the screen for each substance below.)		Negative	Positive	Unclear or Equivocal	Results Not Valid	Not Assessed
5. Amphetamines	<b>LBTEST</b>	0	1 <b>LBORRES</b>	2	3	8
6. Barbiturates		0	1	2	3	8
7. Benzodiazepines		0	1	2	3	8
8. Methadone		0	1	2	3	8
9. Tricyclic Antidepressants		0	1	2	3	8
10. Cocaine metabolites		0	1	2	3	8
11. Methamphetamines		0	1	2	3	8
12. Opiates/Morphine		0	1	2	3	8
13. Phencyclidine (PCP)		0	1	2	3	8
14. Cannabinoids (THC)		0	1	2	3	8

**SALIVA TEST (ST)**

LBCAT=SALIVA TEST

STUDYID

DOMAIN: LB

PAGE 1 OF 1

<b>NIDA-CTN-0015</b>	Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial		Seq. Num.: ____
<b>NODE:</b> ____	<b>STUDY Visit:</b> (circle one)	Baseline Wk1v1 Wk1v2 Wk2v1 Wk2v2	
<b>CTP-SITE ID:</b> ____ - ____		Wk3v1 Wk3v2 Wk4v1 Wk4v2 Wk5v1 Wk5v2	
<b>PARTICIPANT ID:</b> <b>USUBJID</b>		Wk6v1 Wk6v2 1-Wk FUP 3-Month FUP 6-Month FUP	
<b>Assessment Date:</b> ____ / ____ / ____ <b>LBDTC</b> (mm / dd / yyyy)		<b>VISITNUM</b>	<b>EPOCH</b>
<b>FORM COMPLETION STATUS</b>		<b>STAFF ID:</b> ____	
1=CRF Administered 2=Participant refused 3=Staff Member did not Administer		4=Not enough time to Administer 5=No Participant Contact 6=Other	

(Research Assistant/Independent Assessor Completed)

1. Was a Saliva Test performed? \_\_\_\_

0=No

1=Yes

7=Lost Sample

9=Unknown (If 0 or 9, skip to Q4 and enter a comment.)

LBTEST

2. Date Saliva Test was performed: \_\_\_\_ / \_\_\_\_ / \_\_\_\_ (mm/dd/yyyy)

3. Saliva Test result: \_\_\_\_ (If sample was lost, skip question 3.)

0=Negative

1=Positive

9=Unknown

LBTEST

LBBORRES

QNAM=STVISDTC

QLABEL=SALIVA TEST DATE

IDVAR = LBSEQ

4. COMMENTS:

DOMAIN: CO

COREF=SALIVA TEST

COVAL

RDOMAIN=LB

IDVAR= VISITNUM

<b>NIDA-CTN-0015</b>	<b>Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial</b>			Seq. Num.: ____
<b>NODE:</b> ____	<b>STUDY Visit:</b> (circle one)	<b>Baseline</b>		<b>1-Wk FUP</b>
<b>CTP-SITE ID:</b> ____ - ____		<b>3-Month FUP</b>		<b>6-Month FUP</b>
<b>PARTICIPANT ID:</b> <b>USUBJID</b>		<b>EPOCH</b>		<b>VISITNUM</b>
<b>Assessment Date:</b> ____ / ____ / ____ <b>QSDTC</b> (mm / dd / yyyy)		<b>STAFF ID:</b> ____ <b>QSEVAL</b>		
<b>FORM COMPLETION STATUS</b>		1=CRF Administered 2=Participant refused 3=Staff Member did not Administer 4=Not enough time to Administer 5=No Participant Contact 6=Other		

(Independent Assessor Completed)

**Problem Area****QSTEST**

1. Global
2. PTSD
3. Depression
4. Alcohol Abuse/Dependence
5. Cocaine Abuse/Dependence
6. Heroin Abuse/Dependence
7. Marijuana Abuse/Dependence
8. Sedatives Abuse/Dependence
9. Other Drugs: Abuse/Dependence

specify: \_\_\_\_\_

**Current Severity**  
(Use codes below)**QSORRES**
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_
**SEVERITY CODES**

1 = no pathology  
 2 = minimal pathology or sub threshold symptoms  
 3 = mild pathology  
 4 = moderate pathology  
 5 = moderately severe pathology  
 6 = severe pathology  
 7 = extreme pathology  
 8 = not assessed  
 9 = not applicable



## RANDOMIZATION (RAN)

## STUDYID

NIDA-CTN-0015	Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial		Seq. Num.: ____
NODE: ____	STUDY Visit: (circle one)	Baseline	
CTP-SITE ID: ____ - ____		EPOCH VISITNUM	
PARTICIPANT ID: USUBJID			
Assessment Date: ____ / ____ / ____	SCDTC/DSDTC (mm / dd / yyyy)		STAFF ID: ____
FORM COMPLETION STATUS	1-CRF Administered 2-Participant refused 3-Staff Member did not Administer 4-Not enough time to Administer 5-No Participant Contact 6-Other		

(Research Assistant Completed)

SC.SCORRES

SC.SCTEST

YES	NO	
1	0	A. Does the Participant continue to meet eligibility criteria?
1	0	B. Is the Participant currently taking psychotropic medication?

SC.SCORRES

SC.SCTEST

YES	NO	RANDOMIZATION
1	0	1. Was Participant randomized? (If no, skip to question 3a. If yes, continue to question 1a)
		1.a. ____ / ____ DM.RFSTDTC Date of Randomization (mm / dd / yyyy)
		2.a. ____ Randomization number.
		2.b. ____ Randomization Group Assignment? 1 - Experimental (Seeking Safety) 2 - Control (Women's Health Education)

DM.ARM

DS.DSOCCUR

DS.DSTERM

YES	NO	If not randomized, reasons not randomized:
1	0	3.a. Failed to return to clinic DS.DSCAT=DISPOSITION EVENT
1	0	3.b. Declined study participation (Specify in comments below)
1	0	3.c. Moved from area (current or pending)
1	0	3.d. Incarceration (current or pending)
1	0	3.e. Death
1	0	3.f. Failed to meet inclusion criteria or met exclusion criteria
1	0	3.g. Other (If other, then specify in 3h)
		3.h. Specify Other: _____
		4. Comments: _____
		DOMAIN: CO
		COREF DISPOSITION EVENT
		Variables COVAL
		RDOMAIN=DS
		IDVAR=VISITNUM

## THERAPY SESSION ATTENDANCE (TSA)

TUCAT=THERAPY SESSION ATTENDANCE

PAGE 1 OF 1

<b>NIDA-CTN-0015</b>	Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial		Seq. Num.: ____	
NODE: ____	STUDY Visit: (circle one)	EPOCH VISITNUM	Wk1v1	Wk1v2
CTP-SITE ID: ____ - ____			Wk3v1	Wk3v2
PARTICIPANT ID: <b>USUBJID</b>			Wk5v1	Wk5v2
Assessment Date: ____ / ____ / ____	<b>TUDTC</b> (mm / dd / yyyy)	STAFF ID: ____ <b>TUEVAL</b> ____		
____ FORM COMPLETION STATUS	1=CRF Administered 2=Participant refused 3=Staff Member did not Administer		4=Not enough time to Administer 5=No Participant Contact 6=Other	

(Research Assistant Completed)

<b>Session Attendance</b> <b>TUTEST/TUTESTCD</b>	
<b>TUORRES</b> ____	1. Study group: 1=Experimental (Seeking Safety) 2=Control (Women's Health Education)
____	2a. Session topic number (see box at bottom for details)
____	2b. Session cycle number (Not the same as 2a)
____	3. Did the participant personally attend this therapy session? 1=Yes (skip to question 9) 0=No (continue)
<b>Missed Session</b> <b>TUTEST/TUTESTCD</b>	
<b>TUORRES</b> ____	4. Did the participant communicate with the research staff about this absence? 1=Yes 0=No
____	5. Date of last contact with participant: ____ / ____ / ____ (mm/dd/yyyy)
____	6. Count the number of consecutive missed sessions since the last contact between the research staff and the participant. (Including the current session)
____	7. Did the participant view a taped version of the session? 1=Yes (continue) 0=No (skip to question 9)
____	8. Enter the date when the missed session videotape was viewed: ____ / ____ / ____ (mm/dd/yyyy)
<b>Next Scheduled Session</b>	
____	9. Date: ____ / ____ / ____ (mm/dd/yyyy)

Session Topics			
<b>Seeking Safety sessions:</b> 1=Safety 2=PTSD: Taking Back Your Power 3=Detaching from Emotional Pain 4=When Substances Control You 5=Taking Good Care of Yourself 6=Compassion		<b>Women's Health Education sessions:</b> 1=Body Systems 2=Female Anatomy 3=Breast Care 4=Infections 5=HIV/AIDS 6=Contraception	
7=Red and Green Flags 8=Honesty 9=Integrating the Split Self 10=Creating Meaning 11=Setting Boundaries in Relationships 12=Healing From Anger		7=Pregnancy 8=STDs 9=Nutrition 10=High Blood Pressure 11=Diabetes 12=Menopause	

## NON-STUDY MEDICAL SERVICES (NSMS) TUCAT=ACTIVE STUDY PHASE

<b>NIDA-CTN-0015</b>	<b>Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial</b>		<b>Seq. Num.:</b> ____
<b>NODE:</b> ____	<b>STUDY Visit:</b> (circle one)	Wk1v1 Wk1v2 Wk2v1 Wk2v2 Wk3v1 Wk3v2	
<b>CTP-SITE ID:</b> ____ - ____		Wk4v1 Wk4v2 Wk5v1 Wk5v2 Wk6v1 Wk6v2	
<b>PARTICIPANT ID:</b> <b>USUBJID</b> ____		<b>EPOCH</b> ____ <b>1-Wk FUP</b> ____ <b>VISITNUM</b> ____	
<b>Assessment Date:</b> ____ / ____ / ____ <b>TUDTC</b> (mm / dd / yyyy)		<b>STAFF ID:</b> ____ <b>TUEVAL</b> ____	
<b>FORM COMPLETION STATUS</b>		1-CRF Administered 2-Participant refused 3-Staff Member did not Administer 4-Not enough time to Administer 5-No Participant Contact 6-Other	

(Research Assistant Completed)

**TUTEST/ TUTESTCD**  
 A. When did the participant last complete this form? \_\_\_\_ / \_\_\_\_ / \_\_\_\_ **TUORRES** (mm/dd/yyyy)

We'd like you to answer these questions for the medical services you've received including those that are part of this outpatient program (but excluding those associated with this study).

Yes	No	Since your last assessment, have you... <b>TUTEST/ TUTESTCD</b>
1	0	<b>TUORRES</b> 1a. Seen a therapist, that is a psychiatrist, psychologist, counselor, or social worker for drug, psychological, or emotional problems? (If no or not answered, then skip to question 2a, below) <b>TUORRES</b> 1b. ____ (If YES), how many times did you see a psychiatrist or psychologist? 1c. ____ (If YES), how many times did you see a counselor or social worker?
1	0	2a. Visited a medical office, not including your therapist? (Include all visits to a physician, nurse, or nurse practitioner, or physician's assistant) (If no or not answered, then skip to question 3a, below) 2b. ____ (If YES), how many visits to a medical office have you had? 2c. ____ (If YES), how many of these visits did you see a doctor?
1	0	3a. Been admitted into a residential program to detoxify or for other services? (If no or not answered, then skip to question 4a, below) 3b. ____ (If YES), how many admissions? 3c. ____ (If YES), how many nights for all stays?
1	0	4a. Been admitted into a hospital to detoxify? (If no or not answered, then skip to question 5a, below) 4b. ____ (If YES), how many admissions? 4c. ____ (If YES), how many nights for all stays?
1	0	5a. Been admitted to the hospital for any other reason? (If no or not answered, then skip to question 6a, below) 5b. ____ (If YES), how many times were you admitted? 5c. ____ (If at least once), how many nights for all stays?
1	0	6a. Visited an emergency room and not been admitted to the hospital? (If no or not answered, then skip to question 7a, below) 6b. ____ (If YES), how many times did you visit the emergency room?
1	0	7a. Attended any 12-step or self – help meetings? (If no or not answered, then end interview) 7b. ____ (If YES), how many times did you attend 12-step or self – help meetings?

## HELPING ALLIANCE QUESTIONNAIRE – COUNSELOR FORM (HAQC)

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<b>NIDA-CTN-0015</b>	<b>Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial</b>		<b>Seq. Num.: ____</b>
<b>NODE:</b> ____	<b>STUDY Visit:</b> (circle one)	<b>Wk2v1</b>	<b>Wk8v1</b>
<b>CTP-SITE ID:</b> ____ - ____		<b>EPOCH</b>	<b>VISITNUM</b>
<b>PARTICIPANT ID:</b> <u>USUBJID</u>			
<b>Assessment Date:</b> ____ / ____ / <u>QSDTC</u> (mm / dd / yyyy)	<b>STAFF ID:</b> <u>QSEVAL</u>		
<b>FORM COMPLETION STATUS</b>	1-CRF Administered 2-Participant refused 3-Staff Member did not Administer 4-Not enough time to Administer 5-No Participant Contact 6-Other		

(Counselor Completed)

**Instructions:** These are ways that a person may feel or behave in relation to another person – their client. Consider carefully your relationship with your client, and then mark each statement according to how strongly you agree or disagree. Please mark every one.

#	QSTEST/QSTESTCD	QSORRES					
		Strongly Disagree	Disagree	Slightly Disagree	Slightly Agree	Agree	Strongly Agree
1	The client feels she can depend upon me.	1	2	3	4	5	6
2	She feels I understand her.	1	2	3	4	5	6
3	She feels I want her to achieve her goals.	1	2	3	4	5	6
4	At times, the client distrusts my judgment.	1	2	3	4	5	6
5	The client feels she is working together with me in a joint effort.	1	2	3	4	5	6
6	I believe we have similar ideas about the nature of her problems.	1	2	3	4	5	6
7	The client generally respects my views about her.	1	2	3	4	5	6
8	The client believes the procedures used in her therapy are <u>not</u> well-suited to her needs.	1	2	3	4	5	6
9	The client likes me as a person.	1	2	3	4	5	6
10	In most sessions, we find a way to work on her problems together.	1	2	3	4	5	6
11	The client believes I relate to her in ways that <u>slow up</u> the progress of the therapy.	1	2	3	4	5	6
12	The client believes a good relationship has formed between us.	1	2	3	4	5	6
13	The client believes I am experienced in helping people.	1	2	3	4	5	6
14	I want very much for the client to work out her problems.	1	2	3	4	5	6
15	The client and I have meaningful exchanges.	1	2	3	4	5	6
16	The client and I sometimes have <u>unprofitable</u> exchanges.	1	2	3	4	5	6
17	From time to time, we both talk about the same important events in her past.	1	2	3	4	5	6
18	The client believes I like her as a person.	1	2	3	4	5	6
19	At times, the client sees me as distant.	1	2	3	4	5	6

## HELPING ALLIANCE QUESTIONNAIRE – PARTICIPANT (HAQP)

PAGE 1 OF 1

NIDA-CTN-0015	Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial		Seq. Num.: ____
NODE: ____	STUDY Visit: (circle one)	Wk2v1 Wk2v2 Wk3v1 Wk3v2	
CTP-SITE ID: ____ - ____		Wk6v1 Wk6v2 1-Wk FUP	
PARTICIPANT ID: <u>USUBJID</u>		EPOCH	VISITNUM
Assessment Date: ____ / ____ / ____	QSDTC (mm / dd / yyyy)	STAFF ID: ____	QSEVAL
FORM COMPLETION STATUS	1=CRF Administered 2=Participant refused 3=Staff Member did not Administer 4=Not enough time to Administer 5=No Participant Contact 6=Other		

(Research Assistant Completed)

A. Counselor Id: \_\_\_\_ QSTEST/QSTESTCD QSORRES

*Instructions: These are ways that a person may feel or behave in relation to another person – their counselor. Consider carefully your relationship with your counselor, and then mark each statement according to how strongly you agree or disagree. Please mark every one.*

#	QSTEST/QSTESTCD	QSORRES					
		Strongly Disagree	Disagree	Slightly Disagree	Slightly Agree	Agree	Strongly Agree
1	I feel I can depend upon the counselor.	1	2	3	4	5	6
2	I feel the counselor understands me.	1	2	3	4	5	6
3	I feel the counselor wants me to achieve my goals.	1	2	3	4	5	6
4	At times, I distrust the counselor's judgment.	1	2	3	4	5	6
5	I feel I am working together with the counselor in a joint effort.	1	2	3	4	5	6
6	I believe we have similar ideas about the nature of my problems.	1	2	3	4	5	6
7	I generally respect the counselor's views about me.	1	2	3	4	5	6
8	The procedures used in my therapy are <u>not</u> well-suited to my needs.	1	2	3	4	5	6
9	I like the counselor as a person.	1	2	3	4	5	6
10	In most sessions, the counselor and I find a way to work on my problems together.	1	2	3	4	5	6
11	The counselor relates to me in ways that <u>slow up</u> the progress of the therapy.	1	2	3	4	5	6
12	A good relationship has formed with my counselor.	1	2	3	4	5	6
13	The counselor appears to be experienced in helping people.	1	2	3	4	5	6
14	I want very much to work out my problems.	1	2	3	4	5	6
15	The counselor and I have meaningful exchanges.	1	2	3	4	5	6
16	The counselor and I sometimes have <u>unprofitable</u> exchanges.	1	2	3	4	5	6
17	From time to time, we both talk about the same important events in my past.	1	2	3	4	5	6
18	I believe the counselor likes me as a person.	1	2	3	4	5	6
19	At times, the counselor seems distant.	1	2	3	4	5	6

## SEEKING SAFETY FEEDBACK QUESTIONNAIRE (SSQ) STUDYID

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<b>NIDA-CTN-0015</b>		Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial		Seq. Num.: ____	
NODE: ____		STUDY Visit: (circle one)	Wk0v2 1-Wk FUP		
CTP-SITE ID: ____ - ____					
PARTICIPANT ID: ____ <b>USUBJID</b>		<b>EPOCH</b>		<b>VISITNUM</b>	
Assessment Date: ____ / ____ / ____ <b>QSDTC</b> (mm / dd / yyyy)		STAFF ID: ____		<b>QSEVAL</b>	
FORM COMPLETION STATUS		1=CRF Administered 2=Participant refused 3=Staff Member did not Administer		4=Not enough time to Administer 5=No Participant Contact 6=Other	

(Research Assistant Completed)

Your honest feedback about the *Seeking Safety* treatment would be greatly appreciated, so that possible future revisions of it can be as helpful as possible.

QSTEST/QSTESTCD

QSORRES

		Greatly harmful	Somewhat harmful	A little harmful	Neutral	A little helpful	Somewhat helpful	Greatly helpful	N/A (missed session)
	How helpful is the <u>treatment</u> ?								
1	How helpful is the treatment overall?	-3	-2	-1	0	1	2	3	-9
2	How helpful is the treatment for PTSD and substance abuse?	-3	-2	-1	0	1	2	3	-9
3	How helpful is the treatment for PTSD alone?	-3	-2	-1	0	1	2	3	-9
4	How helpful is the treatment for substance abuse alone?	-3	-2	-1	0	1	2	3	-9
	How helpful are each of the <u>topics</u> ?								
5	Safety	-3	-2	-1	0	1	2	3	-9
6	PTSD: Taking Back Your Power	-3	-2	-1	0	1	2	3	-9
7	Detaching from Emotional Pain (Grounding)	-3	-2	-1	0	1	2	3	-9
8	When Substances Control You	-3	-2	-1	0	1	2	3	-9
9	Taking Good Care of Yourself	-3	-2	-1	0	1	2	3	-9
10	Compassion	-3	-2	-1	0	1	2	3	-9
11	Red and Green Flags	-3	-2	-1	0	1	2	3	-9
12	Honesty	-3	-2	-1	0	1	2	3	-9
13	Integrating the Split Self	-3	-2	-1	0	1	2	3	-9
14	Creating Meaning	-3	-2	-1	0	1	2	3	-9
15	Setting Boundaries in Relationships	-3	-2	-1	0	1	2	3	-9
16	Healing from Anger	-3	-2	-1	0	1	2	3	-9



QSCAT      STUDYID

**WOMEN'S HEALTH EDUCATION FEEDBACK QUESTIONNAIRE (WHQ)**

DOMAIN: QS

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<b>NIDA-CTN-0015</b>	<b>Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial</b>		Seq. Num.: ____
<b>NODE:</b> ____	<b>STUDY Visit:</b> (circle one)	Wk8v2	1-Wk FUP
<b>CTP-SITE ID:</b> ____ - ____		<b>EPOCH</b>	<b>VISITNUM</b>
<b>PARTICIPANT ID:</b> ____ <b>USUBJID</b> ____			
<b>Assessment Date:</b> ____ / ____ / ____ <b>QSDTC</b> (mm / dd / yyyy)		<b>STAFF ID:</b> ____ <b>QSEVAL</b> ____	
<b>FORM COMPLETION STATUS</b>	1=CRF Administered 2=Participant refused 3=Staff Member did not Administer 4=Not enough time to Administer 5=No Participant Contact 6=Other		

(Research Assistant Completed)

Your honest feedback about the *Women's Health Group* would be greatly appreciated, so that possible future revisions of it can be as helpful as possible.

QSTEST/QSTESTCD		QSORRES							
		Greatly harmful	Somewhat harmful	A little harmful	Neutral	A little helpful	Somewhat helpful	Greatly helpful	N/A (Missed Session)
1	How helpful is the group overall?	-3	-2	-1	0	1	2	3	-9
	How helpful are each of the topics?								
2	Basic Human Biology-What Are My Body's Systems?	-3	-2	-1	0	1	2	3	-9
3	The Female Reproductive Systems	-3	-2	-1	0	1	2	3	-9
4	Women's health issues (part one): Breast Care	-3	-2	-1	0	1	2	3	-9
5	Women's health issues (part two): Vaginitis	-3	-2	-1	0	1	2	3	-9
6	Introduction to HIV/AIDS	-3	-2	-1	0	1	2	3	-9
7	Contraception and Safer Sex	-3	-2	-1	0	1	2	3	-9
8	Pregnancy and Childbirth	-3	-2	-1	0	1	2	3	-9
9	Sexually Transmitted Diseases	-3	-2	-1	0	1	2	3	-9
10	Nutrition	-3	-2	-1	0	1	2	3	-9
11	High Blood Pressure	-3	-2	-1	0	1	2	3	-9
12	Diabetes	-3	-2	-1	0	1	2	3	-9
13	Menopause	-3	-2	-1	0	1	2	3	-9

## STUDY TERMINATION - TREATMENT (STT)

STUDYID

DOMAIN: DS

PAGE 1 OF 1

<b>NIDA-CTN-0015</b>		<b>Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial</b>		<b>Seq. Num.: ____</b>	
<b>NODE:</b> ____		<b>STUDY Visit:</b> (circle one)		<b>EPOCH VISITNUM</b>	
<b>CTP-SITE ID:</b> ____ - ____					
<b>PARTICIPANT ID:</b> ____ <b>USUBJID</b> ____					
<b>Assessment Date:</b> ____ / ____ / ____ <b>DSDTC</b> (mm / dd / yyyy)				<b>STAFF ID:</b> ____	
<b>FORM COMPLETION STATUS</b>		1-CRF Administered 2-Participant refused 3-Staff Member did not Administer 4-Not enough time to Administer 5-No Participant Contact 6-Other			

(Research Assistant Completed)

DSCAT= TREATMENT TERMINATION

<b>DSTERM/DSDECOD</b>			1. Date of Treatment Phase completion or early termination: ____ / ____ / ____ <b>DSSTDTC</b> (mm / dd / yyyy)		
<b>YES NO UNK</b>			2. Number of group therapy sessions attended by the Participant.		
1	0	-9	<b>QNAM = DSNMSESS, QLABEL = NUMBER OF SESSIONS ATTENDED, IDVAR = DSSEQ</b>		
<b>DSTERM/DSDECOD</b>			3. Did the Participant terminate treatment before the end of the Treatment Phase (early termination)? (If No, then skip to question 10. If Yes or Unk, then complete questions 4a through 10.)		
<b>YES NO UNK</b>			<b>REASON FOR EARLY TERMINATION</b>		
1	0	-9	Complete this section if answered "Yes" or "Unk" in question 3.		
<b>DSTERM/DSDECOD</b>			4a. Was the Participant discharged from the CTP for administrative reasons? (i.e., active disruption of CTP procedures, non-compliance with CTP rules, etc.) (If Yes, answer 4b. If No or UNK, skip to 5a.)		
<b>DSTERM/DSDECOD</b>			4b. If Yes, date of CTP discharge: ____ / ____ / ____ <b>DSSTDTC</b> (mm/dd/yyyy)		
1	0	-9	5a. Was the Participant discontinued from the study for administrative reasons? (i.e., active disruption of counseling, protocol non-compliance, etc.) (If Yes, answer 5b and 5c. If No or UNK, skip to 6a.)		
<b>DSTERM/DSDECOD</b>			5b. If Yes, date of study discontinuance: ____ / ____ / ____ <b>DSSTDTC</b> (mm/dd/yyyy)		
1	0	-9	5c. Was the Participant discontinued for missing 4 consecutive scheduled visits without contact with the RA/IA?		
<b>DSTERM/DSDECOD</b>			6a. Was the participant discontinued from the study for clinical reasons? (i.e., concurrent illness, serious adverse events, etc.) (If Yes, answer 6b. If No or UNK, skip to 7.)		
<b>DSTERM/DSDECOD</b>			6b. If Yes, date of study discontinuance: ____ / ____ / ____ <b>DSSTDTC</b> (mm/dd/yyyy)		
1	0	-9	7. Was the Participant discontinued at her request?		
1	0	-9	8. Did the Participant discontinue the protocol for another reason? (If Yes, then specify in question 9.)		
<b>DSTERM/DSDECOD</b>			9. If any question above was answered Yes, then provide details: _____ _____ _____ <b>DOMAIN: CO</b> <b>COREF=TREATMENT TERMINATION</b> Variables COVAL <b>RDOMAIN=DS</b> <b>IDVAR=VISITNUM</b>		
<b>CONTINUATION</b>					
1	0	-9	10. Will the participant continue into the Follow-up phase of the study?		

**QNAM = DSCONTIN, QLABEL = CONTINUE INTO FOLLOW-UP PHASE?, IDVAR = DSSEQ**



## ADDICTION SEVERITY INDEX-LITE FOLLOW-UP (ASF) =QSCAT

<b>NIDA-CTN-0015</b>	Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial		Seq. Num.: ____
NODE: ____	STUDY Visit: (circle one)	EPOCH VISITNUM	
CTP-SITE ID: ____ - ____		1-Wk FUP 3-Month FUP 6-Month FUP 12-Month FUP	
PARTICIPANT ID: ____ <b>USUBJID</b>			
Assessment Date: ____ / ____ / ____ <b>QSDTC</b> (mm / dd / yyyy)		STAFF ID: ____ <b>QSEVAL</b>	
FORM COMPLETION STATUS		1-CRF Administered 2-Participant refused 3-Staff Member did not Administer 4-Not enough time to Administer 5-No Participant Contact 6-Other	

(Independent Assessor Completed)

Participant Date of Birth (mm/dd/yyyy): \_\_\_\_ / \_\_\_\_ / \_\_\_\_

### Composite Scores

(for site use only):

Medical: ____	Legal: ____
Employment: ____	Family: ____
Drug: ____	Psychiatric: ____
Alcohol: ____	

## KEY:

Patient Rating Scale
0 = Not at all
1 = Slightly
2 = Moderately
3 = Considerably
4 = Extremely

## Introducing the ASI

Seven potential problem areas: Medical, Employment/Support Status, Alcohol, Drug, Legal, Family/Social, and Psychological. All clients receive this same standard interview. All information gathered is confidential.

There are two time periods we will discuss:

1. The past 30 days
2. Since your last ASI

**Patient Rating Scale:** Patient input is important. For each area, I will ask you to use this scale to let me know how bothered you have been by any problems in each section. I will also ask you how important treatment is for you for the area being discussed.

Please refer to the Patient Rating Scale in the adjacent key.

If you are uncomfortable giving an answer, then don't answer.

*Please do not give inaccurate information!*

## Interviewer Instructions

1. Leave no blanks.
2. Make plenty of Comments (if another person reads this ASI, they should have a relatively complete picture of the client's perceptions of his/her problems).
3. Throughout the ASI, when noted: **X** = Question not answered.  
**N** = Question not applicable.
4. Terminate interview if client misrepresents two or more sections.
5. When noting comments, please write the question number.

**HALF TIME RULE:**

If a question asks the number of months, round up periods of 14 days or more to 1 month. Round up 6 months or more to 1 year.

**CONFIDENCE RATINGS:**

- ⇒ Last two items in each section.
  - ⇒ Do not over interpret.
  - ⇒ Denial does not warrant misrepresentation.
  - ⇒ Misrepresentation = overt contradiction in information.
- Probe and make plenty of comments!*



CTP - Site ID ____ - ____	Participant ID <u>USUBJID</u>	Assessment Date: ____ / ____ / <u>QSDTC</u> m m d d y y y y
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**GENERAL INFORMATION** =QSSCAT

QSORRES QSTEST

G9. Contact code:  
 1=In person  
 2=Telephone (intake ASI must be in person)  
 3=Mail  
 X=Not Answered

\_\_\_\_ G12. Special:  
 1=Patient terminated  
 2=Patient refused  
 3=Patient unable to respond  
 N=Not Applicable

\_\_\_\_ G19. Have you been in a controlled environment in the past 30 days? A place, theoretically, without access to drugs/alcohol.  
 1=No 5=Psychiatric Treatment  
 2=Jail 6=Other (specify \_\_\_\_\_)  
 3=Alcohol or Drug Treatment X=Not Answered  
 4=Medical Treatment

\_\_\_\_ G20. How many days? "NN" if question G19 is "No". Refers to total number of days detained in the past 30 days. (XX=Not Answered)

Comments:

QSEVLINT=-P30D QSORRESU=DAY

CTP - Site ID _____ - _____	Participant ID _____ <b>USUBJID</b> _____	Assessment Date: ____ / ____ / ____ <b>QSDTC</b> m m d d y y y y
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**MEDICAL STATUS =QSSCAT****QSORRES****QSTEST**

- M1. Since your last ASI, how many times have you been hospitalized for medical problems?  
Include O.D.'s, D.T.'s. Exclude detox, alcohol/drug, and psychiatric treatment and childbirth (if no complications). Enter the number of overnight hospitalizations for medical problems. (XX=Not Answered)
- \_\_\_\_\_ M4. Are you taking any prescribed medication on a regular basis for a physical problem?  
0=No, 1=Yes  
Medication prescribed by a MD for medical conditions; not psychiatric medicines. Include medicines prescribed whether or not the patient is currently taking them. The intent is to verify chronic medical problems. (X=Not Answered)  
If "Yes," specify: \_\_\_\_\_
- \_\_\_\_\_ M5. Do you receive a pension for a physical disability? (X=Not Answered)  
0=No, 1=Yes  
Include Workers' compensation, exclude psychiatric disability.  
If "Yes," specify: \_\_\_\_\_
- \_\_\_\_\_ M6. How many days have you experienced medical problems in the past 30 days? **QSORRESU=DAY QSEVLINT=-P30D**  
Do not include ailments directly caused by drugs/alcohol. Include flu, colds, etc. Include serious ailments related to drugs/alcohol, which would continue even if the patient were abstinent (e.g., cirrhosis of liver, abscesses from needles, etc.). (X=Not Answered)
- For Questions M7 & M8, please ask the patient to use the Patient Rating scale.
- \_\_\_\_\_ M7. How troubled or bothered have you been by these medical problems in the past 30 days? **QSEVLINT=-P30D**  
Restrict response to problem days of Question M6. (X=Not Answered)
- \_\_\_\_\_ M8. How important to you now is treatment for these medical problems?  
Refers to the need for new or additional medical treatment by the patient. (X=Not Answered)

**CONFIDENCE RATINGS****THIS DATA NOT ENTERED**Is the above information significantly distorted by:

- \_\_\_\_\_ M10. Patient's misrepresentation?  
0=No, 1=Yes
- \_\_\_\_\_ M11. Patient's inability to understand?  
0=No, 1=Yes

Comments:

CTP - Site ID ____ - ____	Participant ID <u>USUBJID</u>	Assessment Date: ____ / ____ / ____ m m d d y y y y
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**EMPLOYMENT/SUPPORT STATUS =QSSCAT**

\_\_\_\_ / \_\_\_\_  
a. Yrs. / b. Mos.

**QSORRES**

\_\_\_\_  
Mos.

0=No, 1=Yes

0=No, 1=Yes

\_\_\_\_

0=No, 1=Yes

\_\_\_\_

\_\_\_\_

**Max=\$99999**

\$ \_\_\_\_\_

\$ \_\_\_\_\_

\$ \_\_\_\_\_

\$ \_\_\_\_\_

\$ \_\_\_\_\_

\$ \_\_\_\_\_

\$ \_\_\_\_\_

\_\_\_\_

**Max = 99**

E1. Education completed since your last ASI? **QSTEST**  
GED = 12 years. Include formal education only. (XX=Not Answered)

E2. Training or technical education completed since your last ASI:  
Formal/organized training only. For military training, only include training that can be used in civilian life (i.e., electronics or computers). (XX=Not Answered)

E4. Do you have a valid driver's license? Valid license; not suspended/revoked. (X=Not Answered)

E5. Do you have an automobile available? (If answer to E4 is "No", then E5 must be "No")  
Does not require ownership, only requires availability on a regular basis. (X=Not Answered)

E7. Usual (or last) occupation since your last ASI?  
(specify: \_\_\_\_\_)  
(Use Hollingshead Categories Reference Sheet) (X=Not Answered)

E9. Does someone contribute the majority of your support?  
Is patient receiving any regular support (i.e., cash, food, housing) from family/friend? Include spouse's contribution; exclude support by an institution. (X=Not Answered, N=Not Applicable)

E11. How many days were you paid for working in the past 30 days?  
Include "under the table" work, paid sick days, and vacation. (XX=Not Answered)

**QSORRESU=DAY QSEVLINT=-P30D**

**For questions E12-E17: How much money did you receive from the following sources in the past 30 days?**

**QSEVLINT=-P30D**

E12. Employment? (Net or "take home" pay, include any "under the table" money.) (XXXXX=Not Answered)

E13. Unemployment Compensation? (XXXXX=Not Answered)

E14. Welfare? (Include food stamps, transportation money provided by an agency to go to and from treatment.) (XXXXX=Not Answered)

E15. Pensions, benefits or Social Security? (Include disability, pensions, retirement, veteran's benefits, SSI & workers' compensation.) (XXXXX=Not Answered)

E16. Mate, family or friends? (Money for personal expenses, (i.e., clothing), include unreliable sources of income (e.g., gambling). Record cash payments only, include windfalls (unexpected), money from loans, gambling, inheritance, tax returns, etc.). (XXXXX=Not Answered)

E17. Illegal? (XXXXX=Not Answered)  
Cash obtained from drug dealing, stealing, fencing stolen goods, gambling, prostitution, etc. Do Not attempt to covert drugs exchanged to a dollar value.

E18. How many people depend on you for the majority of their food, shelter, etc.? Must be regularly depending on patient, do include all money/child support, do not include the patient or self-supporting spouse, etc. (XX=Not Answered)

Comments:

**QSORRESU=DOLLAR**

CTP - Site ID _____ - _____	Participant ID <u>USUBJID</u>	Assessment Date: ____ / ____ / ____ m m d d y y y y
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QSORRES

QSTEST

- E19. How many days have you experienced employment problems in the past 30 days?  
Include inability to find work, if they are actively looking for work, or problems with present job in which that job is jeopardized. (XX=Not Answered)  
QSEVLINT=-P30D QSORRESU=DAYS

**For Questions E20 & E21, ask the patient to use the Patient Rating scale.**

The patient's ratings in Questions E20 & E21 refer to Question E19. Stress help in finding or preparing for a job, not giving them a job.

- \_\_\_\_\_ E20. How troubled or bothered have you been by these employment problems in the past 30 days?  
If the patient has been incarcerated or detained during the past 30 days, they cannot have employment problems. (X=Not Answered)
- \_\_\_\_\_ E21. How important to you now, is counseling for these employment problems? (X=Not Answered)

#### CONFIDENCE RATINGS

THIS DATA NOT ENTERED

Is the above information significantly distorted by:

- E23. Patient's misrepresentation?

0=No, 1=Yes

- E24. Patient's inability to understand?

0=No, 1=Yes

Comments:

CTP - Site ID ____ - ____	Participant ID ____ <u>USUBJID</u> ____	Assessment Date: ____ / ____ / ____ <u>QSDTC</u> m m d d y y y y
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**DRUG/ALCOHOL USE** =QSSCAT

Route of Administration Types:

1 = Oral 2 = Nasal 3 = Smoking 4 = Non-IV Injection 5 = IV Injection

Note the usual or most recent route. For more than one route, choose the most severe. The routes are listed from least severe to most severe. If Past 30 Days is zero, route should be coded as "N." (XX=Not Answered)

QSEVLINT=-P30D

Substance <u>QSTEST</u>	a. Past 30 Days	c. Route of Admin.	Comments:
D1. Alcohol (any use at all)	<u>QSORRES</u>		<div style="border: 1px solid red; padding: 5px;">           QNAM = QSRTADMN            QLABEL = ROUTE OF ADMIN.            IDVAR = QSSEQ         </div>
D2. Alcohol (to intoxication)	____		
D3. Heroin	____		
D4. Methadone/LAAM (prescribed)	____		
D4a. Methadone/LAAM (illicit)	____		
D5. Other Opiates/Analgesics	____		
D6. Barbiturates	____		
D7. Other Sedatives/Hypnotics/Tranquilizers	____		
D8. Cocaine	____		
D9. Amphetamines	____		
D10. Cannabis	____		
D11. Hallucinogens	____		
D12. Inhalants	____		
D36. Nicotine (tobacco products)	____		
D13. More than 1 substance per day (including alcohol, excluding nicotine)	____		

QSORRES D14. According to the interviewer, which substance(s) is/are the major problem?  
 Interviewer should determine the major drug or drugs of abuse (excluding Nicotine use). Code the number next to the drug in questions 01-12, (code prescribed or illicit methadone as "04"). "00" = no problem, "15" = alcohol & one or more drugs, "16" = more than one drug but no alcohol. Ask participant when not clear.  
 (XX=Not Answered)

How many times since your last ASI have you:

\_\_\_\_ D17. Had Alcohol DT's? Deltium Tremens (DT's): Occur 24-48 hours after last drink, or significant decrease in alcohol intake. Characterized by shaking, severe disorientation, fever, hallucinations, they usually require medical attention. (XX=Not Answered)

Comments:

CTP - Site ID _____	Participant ID <u>USUBJID</u>	Assessment Date: ____ / ____ / <u>QSDTC</u> m m d d y y y y
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QSTEST/QSTESTCD

QSORRES

How many times since your last ASI have you been treated for:  
Include detoxification, halfway houses, in/outpatient counseling, and AA or NA (if  
3+ meetings within one month period). (XX=Not Answered)

D19. Alcohol abuse?

D20. Drug abuse?

How many of these were detox only?

D21. Alcohol? If D19 = "00", then question D21 is "NN" (XX=Not Answered)

D22. Drugs? If D20 = "00", then question D22 is "NN" (XX=Not Answered)

Max  
=\$99999  
How much money would you say you spent during the past 30  
days on: Only count actual money spent. What is the financial burden caused  
by drugs/alcohol? (XXXXX=Not Answered)

D23. Alcohol?

D24. Drugs?

D25. How many days have you been treated in an outpatient  
setting for alcohol or drugs in the past 30 days? (Include  
AA/NA) (XX=Not Answered)

For questions D28 - D31, please ask the patient to use the  
Patient Rating scale.

The Patient is rating the need for additional substance abuse treatment. (X=Not Answered)

How many days in the past 30 have you experienced:

D26. Alcohol problems? QSEVLINT=-P30D QSORRESU=DAYS

How troubled or bothered have you been in the past 30 days  
by these:

D28. Alcohol problems? QSEVLINT=-P30D

How important to you now is treatment for these:

D30. Alcohol problems?

How many days in the past 30 have you experienced:

D27. Drug problems? QSEVLINT=-P30D QSORRESU=DAYS  
Include: Craving, withdrawal symptoms, disturbing effects of use, or wanting to  
stop and being unable to. (XX=Not Answered)

How troubled or bothered have you been in the past 30 days  
by these:

D29. Drug problems? QSEVLINT=-P30D

How important to you now is treatment for these:

D31. Drug problems?

CONFIDENCE RATINGS THIS DATA NOT ENTERED

Is the above information significantly distorted by:

D34. Patient's misrepresentation?

D35. Patient's inability to understand?

Comments:



CTP - Site ID ____ - ____	Participant ID <u>USUBJID</u>	Assessment Date: ____ / ____ / ____ <b>QSDTC</b> m m d d y y y y
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**LEGAL STATUS =QSSCAT****QSORRES****QSTEST/QSTESTCD**

L2. Are you on parole or probation?  
0=No, 1=Yes Note duration and level in comments. (X=Not Answered)

**How many times since your last ASI have you been arrested and charged with the following:** Include total number of counts, not just convictions. Do not include juvenile (pre-age 18) crimes, unless they were charged as an adult. Include formal charges only. (XX=Not Answered)

Comments:

- |                                      |                                  |
|--------------------------------------|----------------------------------|
| ____ L3. Shoplifting/Vandalism       | ____ L10. Assault                |
| ____ L4. Parole/Probation Violations | ____ L11. Arson                  |
| ____ L5. Drug Charges                | ____ L12. Rape                   |
| ____ L6. Forgery                     | ____ L13. Homicide/Manslaughter  |
| ____ L7. Weapons Offense             | ____ L14. Prostitution           |
| ____ L8. Burglary/Larceny/B&E        | ____ L15. Contempt of court      |
| ____ L9. Robbery                     | ____ L16. Other: (specify _____) |

- \_\_\_\_ L17. How many of these charges resulted in convictions?  
If L3-L16= "00", then L17="NN". Do not include misdemeanor offenses from questions L18-L20 below. Convictions include fines, probation, incarcerations, suspended sentences, and guilty pleas. (XX=Not Answered)

**How many times since your last ASI have you been charged with the following:**

- \_\_\_\_ L18. Disorderly conduct, vagrancy, public intoxication? (XX=Not Answered)
- \_\_\_\_ L19. Driving while intoxicated (DWI)? (XX=Not Answered)
- \_\_\_\_ L20. Major driving violations?  
Moving violations: speeding, reckless driving, no license, etc. (XX=Not Answered)
- \_\_\_\_ Mos. L21. How many months were you incarcerated since your last ASI? (XX=Not Answered) **QSORRESU=MONTH**  
If incarcerated 2 weeks or more, round this up to 1 month. List total number of months incarcerated.
- \_\_\_\_ L24. Are you presently awaiting charges, trial, or sentence? (X=Not Answered)  
0=No, 1=Yes

CTP - Site ID ____ - ____	Participant ID <u>USUBJID</u>	Assessment Date: ____ / ____ / ____ QSDTC m m d d y y y y
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QSORRES

QSTEST

QSEVLINT=-P30D QSORRESU=DAY

Comments:

L25. What for? (Refers to L24.) Use code 03-16, 18-20. If more than one, choose most severe.

Don't include civil cases, unless a criminal offense is involved. (XX=Not Answered, NN= Not Applicable)

03 - Shoplifting

12 - Rape

04 - Probation violation

13 - Homicide

05 - Drug

14 - Prostitution

06 - Forgery

15 - Contempt

07 - Weapons

16 - Other

08 - Burglary

18 - Disorderly conduct

09 - Robbery

19 - DWI

10 - Assault

20 - Major driving violation

11 - Arson

L26. How many days in the past 30, were you detained or incarcerated? QSEVLINT=-P30D QSORRESU=DAY  
Include being arrested and released on the same day. (XX=Not Answered)

L27. How many days in the past 30, have you engaged in illegal activities for profit? QSEVLINT=-P30D QSORRESU=DAY  
Exclude simple drug possession. Include drug dealing, prostitution, selling stolen goods, etc. May be cross- checked with Question E17 under Employment/Family Support Section. (XX=Not Answered)

For questions L28 & L29, ask the patient to use the Patient Rating scale.

L28. How serious do you feel your present legal problems are?  
Exclude civil problems. (X=Not Answered)

L29. How important to you now is counseling or referral for these legal problems?  
Patient is rating a need for additional referral to legal counsel for defense against criminal charges. (X=Not Answered)

CONFIDENCE RATINGS

THIS DATA NOT ENTERED

Is the above information significantly distorted by:

L31. Patient's misrepresentation?

0=No, 1=Yes

L32. Patient's inability to understand?

0=No, 1=Yes

CTP - Site ID _____	Participant ID <u>USUBJID</u>	Assessment Date: ____ / ____ / ____ <u>QSDTC</u> m m d d y y y y
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**FAMILY/SOCIAL RELATIONSHIPS**

=QSSCAT

QSORRES

F1.

Marital Status

QSTEST

1 = Married    3 = Widowed    5 = Divorced  
 2 = Remarried    4 = Separated    6 = Never Married  
 Common-law marriage = "1." (Specify in comments) (X=Not Answered)

\_\_\_\_\_  
 0=No,  
 1=Indifferent,  
 2=Yes

F3. Are you satisfied with this situation? (Refers to Question F1)  
 Satisfied = generally liking the situation. (X=Not Answered)

F4. Living arrangements (Since your last ASI):

1 = With sexual partner & children    6 = With friends  
 2 = With sexual partner alone    7 = Alone  
 3 = With children alone    8 = Controlled Environment  
 4 = With parents    9 = No stable arrangement  
 5 = With family

Choose arrangements most representative of the past 3 years. If there is an even split in time between these arrangements, choose the most recent arrangement. (X=Not Answered)

\_\_\_\_\_  
 0=No,  
 1=Indifferent,  
 2=Yes

F6. Are you satisfied with these arrangements?  
 Refers to response in Question F4. (X=Not Answered)

Do you live with anyone who:

\_\_\_\_\_  
 0=No, 1=Yes

F7. Has a current alcohol problem? (X=Not Answered)

\_\_\_\_\_  
 0=No, 1=Yes

F8. Uses non-prescribed drugs? (X=Not Answered)

\_\_\_\_\_  
 1=Family,  
 2=Friends,  
 3=Alone

F9. With whom do you spend most of your free time?  
 If a girlfriend/boyfriend is considered as a family by patient, then they must refer to them as family throughout this section, not a friend. Family is not to be referred to as "friend." (X=Not Answered)

\_\_\_\_\_  
 0=No,  
 1=Indifferent,  
 2=Yes

F10. Are you satisfied with spending your free time this way?  
 (Refers to Question F9.)  
 A satisfied response must indicate that the person generally likes the situation. (X=Not Answered)

Have you had significant periods in which you have experienced serious problems getting along with: "Serious problems" mean those that endangered the relationship. A "problem" requires contact of some sort, either by telephone or in person.

a. Past 30  
 Days

0= No, 1= Yes, (X= Not Answered, N= Not Applicable)

- \_\_\_\_\_  
 F18. Mother  
 \_\_\_\_\_  
 F19. Father  
 \_\_\_\_\_  
 F20. Brothers/Sisters  
 \_\_\_\_\_  
 F21. Sexual Partner/Spouse  
 \_\_\_\_\_  
 F22. Children  
 \_\_\_\_\_  
 F23. Other Significant Family (Specify \_\_\_\_\_)  
 \_\_\_\_\_  
 F24. Close Friends  
 \_\_\_\_\_  
 F25. Neighbors  
 \_\_\_\_\_  
 F26. Co-workers

Comments:

CTP - Site ID _____	Participant ID _____ <u>USUBJID</u> _____	Assessment Date: ____/____/____ m m d d y y y y
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a. Past 30  
Days

0= No, 1= Yes (X=Not Answered)

QSEVLINT=-P30D QSTEST

QSORRES

Did anyone (Question F18 - F26) abuse you?

F28. Physically? (Caused you physical harm.)

F29. Sexually? (Forced sexual advances/acts.)

How many days in the past 30 have you had serious conflicts:

F30. With your family? (XX= Not Answered) QSEVLINT=-P30D QSORRESU=DAY

For Questions F32 and F34, ask the patient to use the Patient Rating scale.

How troubled or bothered have you been in the past 30 days by these:

F32. Family problems (X= Not Answered)

QSEVLINT=-P30D

How important to you now is treatment or counseling for these:

F34. Family problems

Patient is rating his/her need for counseling for family problems, not whether the family would be willing to attend. (X= Not Answered)

How many days in the past 30 have you had serious conflicts:

F31. With other people (excluding family)? (XX= Not Answered)

QSEVLINT=-P30D

For Questions F33 and F35, ask the patient to use the Patient Rating scale.

How troubled or bothered have you been in the past 30 days by these:

QSEVLINT=-P30D

F33. Social problems (X= Not Answered)

How important to you now is treatment or counseling for these:

F35. Social problems

Include patient's need to seek treatment for such social problems as loneliness, inability to socialize, and dissatisfaction with friends. Patient rating should refer to dissatisfaction, conflicts, or other serious problems. Exclude problems that would be eliminated if patient had no substance abuse. (X= Not Answered)

CONFIDENCE RATING

THIS DATA NOT ENTERED

Is the above information significantly distorted by:

F37. Patient's misrepresentation?

0=No, 1=Yes

F38. Patient's inability to understand?

0=No, 1=Yes

Comments:

CTP - Site ID _____	Participant ID <u>USUBJID</u>	Assessment Date: ____ / ____ / ____ <b>QSDTC</b> m m d d y y y y
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**PSYCHIATRIC STATUS=QSSCAT****QSTEST**

How many times since your last ASI have you been treated for any psychological or emotional problems:

Do not include substance abuse, employment, or family counseling. Treatment episode = a series of more or less continuous visits or treatment days, not the number of visits or treatment days. Enter diagnosis in comments if known.

**QSORRES**

- \_\_\_\_ P1. In a Hospital or inpatient setting? (XX= Not Answered)
- \_\_\_\_ P2. Outpatient/private patient? (XX= Not Answered)
- \_\_\_\_ P3. Do you receive a pension for a psychiatric disability? (X=Not Answered)
- 0=No, 1=Yes

Have you had a significant period of time (that was not a direct result of alcohol/drug use) in which you have:

a. Past 30 Days

0=No, 1=Yes, (X= Not Answered)

- \_\_\_\_ P4. Experienced serious depression-sadness, hopelessness, loss of interest, difficulty with daily function?
- \_\_\_\_ P5. Experienced serious anxiety/tension-uptight, unreasonably worried, inability to feel relaxed?
- \_\_\_\_ P6. Experienced hallucinations-saw things or heard voices that other people did not see or hear?
- \_\_\_\_ P7. Experienced trouble understanding, concentrating, or remembering?

For questions P8-P10, patient could have been under the influence of alcohol/drugs.

- \_\_\_\_ P8. Experienced trouble controlling violent behavior including episodes of rage, or violence? (Patient can be under the influence of alcohol/drugs.)
- \_\_\_\_ P9. Experienced serious thoughts of suicide?  
Patient seriously considered a plan for taking his/her life.
- \_\_\_\_ P10. Attempted suicide? (Include actual suicidal gestures or attempts.)
- \_\_\_\_ P11. Been prescribed medication for any psychological or emotional problems? (Prescribed for the patient by MD. Record "Yes" if a medication was prescribed even if the patient is not taking it.)
- \_\_\_\_ P12. How many days in the past 30 have you experienced these psychological or emotional problems? (This refers to problems noted in Questions P4-P10.) (XX= Not Answered)

Comments:

**QSEVLINT=-P30D QSORRESU=DAY**

CTP - Site ID _____ - _____	Participant ID _____ <u>USUBJID</u> _____	Assessment Date: ____/____/____ m  m     d  d     y  y  y  y
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## QSTEST

For Question P13 & P14, ask the patient to use the Patient Rating scale.

QSORRES

QSEVLINT=-P30D

- \_\_\_\_\_ P13. How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days? (Patient should be rating the problem days from Question P12.) (X= Not Answered)
- \_\_\_\_\_ P14. How important to you now is treatment for these psychological or emotional problems? (X= Not Answered)

## CONFIDENCE RATING

Is the above information significantly distorted by:

0=No, 1=Yes

P22. Patient's misrepresentation?

0=No, 1=Yes

P23. Patient's inability to understand?

Comments:

<b>NIDA-CTN-0015</b>	<b>Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial</b>		<b>Seq. Num.:</b> ____
<b>NODE:</b> ____	<b>STUDYID</b>	<b>EPOCH</b>	<b>VISITNUM</b>
<b>CTP-SITE ID:</b> ____ - ____	<b>STUDY Visit:</b> (circle one)	1-Wk FUP	3-Month FUP
<b>PARTICIPANT ID:</b> ____ <b>USUBJID</b>		6-Month FUP	12-Month FUP
<b>Assessment Date:</b> ____ / ____ / ____	<b>QSDTC</b> (mm / dd / yyyy)	<b>STAFF ID:</b> ____ <b>QSEVAL</b> ____	
<b>FORM COMPLETION STATUS</b>	1=CRF Administered 2=Participant refused 3=Staff Member did not Administer	4=Not enough time to Administer 5=No Participant Contact 6=Other	

(Independent Assessor Completed)

For questions 18 and 19, ask the Participant to consider only events that have happened since her last interview.

(Please note that the question numbering has been preserved from the Addendum CRF, and, therefore, the questions are not numbered sequentially.)

Yes	No	NA	<b>QSTEST</b>	
1	0	-9	<b>18a.</b>	Since our last interview, has anyone used physical violence (such as being slapped, pushed, hit or punched) or the threat of physical violence against you? <i>(If yes, ask questions 18b-18f. If no or not answered, skip to question 19a.)</i>
				If yes, how was this person related to you:
1	0	-9	<b>18b.</b>	Spouse?
1	0	-9	<b>18c.</b>	Other family member?
1	0	-9	<b>18d.</b>	Partner/significant other?
1	0	-9	<b>18e.</b>	Stranger?
1	0	-9	<b>18f.</b>	Did you receive medical treatment for any injuries as a result of physical violence against you?
<b>QSORRES</b>				
Yes	No	NA		
1	0	-9	<b>19a.</b>	Since our last interview, has anyone used sexual violence (forcing you to do anything sexual) or the threat of sexual violence against you? <i>(If yes, ask questions 19b-19f. If no or not answered, skip to question 22.)</i>
				If yes, how was this person related to you:
1	0	-9	<b>19b.</b>	Spouse?
1	0	-9	<b>19c.</b>	Other family member?
1	0	-9	<b>19d.</b>	Partner/significant other?
1	0	-9	<b>19e.</b>	Stranger?
1	0	-9	<b>19f.</b>	Did you receive medical treatment for any injuries as a result of sexual violence against you?



CTP - Site ID ____-____	Participant ID <b>USUBJID</b>	Assessment Date: ____ / ____ / <b>QSDTC</b> m m         d d         v v v v
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For questions 22 through 26, ask the Participant to consider how she feels currently.

QSORRES		Overall Health	QSTEST
___	22.	Please rate your current health status in general: 1 = Excellent 2 = Good 3 = Fair 4 = Poor 5 = Very poor -9 = Not answered	
		Please tell me how much you agree or disagree with the following statements:	
___	23.	I am somewhat ill. 1 = Strongly agree 2 = Somewhat agree 3 = Neither agree nor disagree 4 = Somewhat disagree 5 = Strongly disagree -9 = Not answered	
___	24.	I am as healthy as anybody I know. 1 = Strongly agree 2 = Somewhat agree 3 = Neither agree nor disagree 4 = Somewhat disagree 5 = Strongly disagree -9 = Not answered	
___	25.	My health is excellent. 1 = Strongly agree 2 = Somewhat agree 3 = Neither agree nor disagree 4 = Somewhat disagree 5 = Strongly disagree -9 = Not answered	
___	26.	I have been feeling bad lately. 1 = Strongly agree 2 = Somewhat agree 3 = Neither agree nor disagree 4 = Somewhat disagree 5 = Strongly disagree -9 = Not answered	

## TRAUMA SPECIFIC TREATMENT (TST) =TUCAT

STUDYID

PAGE 1 OF 1

<b>NIDA-CTN-0015</b>		Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial		Seq. Num.: ____	
NODE: ____	STUDY Visit: (circle one)	EPOCH		VISITNUM	
CTP-SITE ID: ____ - ____		1-Week FUP		3-Month FUP	
PARTICIPANT ID: ____ <b>USUBJID</b>		6-Month FUP		12-Month FUP	
Assessment Date: ____ / ____ / ____ <b>TUDTC</b> (mm / dd / yyyy)			STAFF ID: ____ <b>QSEVAL</b>		
FORM COMPLETION STATUS		1=CRF Administered 2=Participant refused 3=Staff Member did not Administer		4=Not enough time to Administer 5=No Participant Contact 6=Other	

(Independent Assessor Completed)

Complete this questionnaire immediately after the NSMF (Non-Study Medical Services – Follow-Up), or the NSMS at the 1-Week Follow-Up visit.

TUORRES

Yes	No	TUTEST/TUTESTCD	
1	0	1.	Since your last assessment, have you received treatment from a counselor/psychiatrist/psychologist/social worker where the primary focus was on trauma related issues or symptoms?  (If NO OR NOT ANSWERED, THEN END QUESTIONNAIRE. OTHERWISE, COMPLETE Q2 AND Q3.)
		2.	____ (If YES) How many times did you see a counselor/psychiatrist/psychologist/social worker for trauma specific treatment <u>since your last assessment</u> ?
		3.	____ (If YES) How many times did you see a counselor/psychiatrist/psychologist/social worker for trauma specific treatment <u>in the last 30 days</u> ?

## STUDY BLIND INTEGRITY (SBI) =QSCAT

<b>NIDA-CTN-0015</b>	<b>Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial</b>		<b>Seq. Num.:</b> ____
<b>NODE:</b> ____	<b>STUDY Visit:</b> (circle one)	<b>VISITNUM</b> <b>EPOCH</b>	
<b>CTP-SITE ID:</b> ____ - ____		1-Wk FUP   3-Month FUP   6-Month FUP   12-Month FUP	
<b>PARTICIPANT ID:</b> ____	<b>USUBJID</b>		
<b>Assessment Date:</b> ____ / ____ / ____		<b>QSDTC</b> (mm / dd / yyyy)	<b>STAFF ID:</b> ____ <b>QSEVAL</b> ____
<b>FORM COMPLETION STATUS</b>		1-CRF Administered 2-Participant refused 3-Staff Member did not Administer	4-Not enough time to Administer 5-No Participant Contact 6-Other

(Independent Assessor Completed)

QSORRES

QSTEST/QSTESTCD

- \_\_\_\_ 1. Were you informed of this Participant's group assignment? (e.g. Was the study blind broken for this Participant?)  
       1 = Yes (Answer question 2)  
       0 = No
- \_\_\_\_ 2. If yes, to which group was the Participant assigned?  
       1 = Experimental (Seeking Safety)  
       2 = Control (Women's Health Education)

## STUDY TERMINATION - FOLLOW-UP (STF)

STUDYID

DOMAIN: DS PAGE 1 OF 1

<b>NIDA-CTN-0015</b>		Women's Treatment For Trauma And Substance Use Disorders: A Randomized Clinical Trial		Seq. Num.: ____
NODE: ____		STUDY Visit: (circle one)	EPOCH	VISITNUM
CTP-SITE ID: ____ - ____			12-Month FUP	
PARTICIPANT ID: ____	USUBJID		EPOCH VISITNUM	
Assessment Date: ____ / ____ / ____		DSDTC (mm / dd / yyyy)	STAFF ID: ____	
FORM COMPLETION STATUS		1=CRF Administered 2=Participant refused 3=Staff Member did not Administer 4=Not enough time to Administer 5=No Participant Contact 6=Other		

(Independent Assessor Completed)

DSCAT=DISPOSITION EVENT

DSTERM/DSDECOD			DM.RFENDTC
1. Date of Follow-Up Phase completion or early termination: ____			DSSDTC (mm / dd / yyyy)
2. Number of Follow-Up Phase visits completed.			
YES	NO	UNK	QNAM = DSNUMVIS, QLABEL = NUMBER OF FOLLOW-UP VISITS, IDVAR = DSSEQ
1	0	-9	
3. Did the Participant terminate before the end of the Follow-Up Phase (early termination)? (If No, then end questionnaire. If Yes or UNK, then complete questions 4 through 8.)			
DSOCCUR			
YES	NO	UNK	
1	0	-9	
4. Did the Participant refuse to continue (discontinue at her request)?			DSTERM/DSDECOD
1	0	-9	
5. Was the Participant lost to follow-up (lost contact)?			
1	0	-9	
6. Was the Participant terminated for clinical reasons?			
1	0	-9	
7. Was the Participant terminated for some other reason? (If yes, describe in question 8.)			
8. If any question above was answered Yes, then provide details:			
			DOMAIN: CO
			COREF=STUDY TERMINATION FOLLOW UP
			Variables COVAL
			RDOMAIN=DS
			IDVAR=VISITNUM