NIDA

Annotated Design For Trial: CTN0028

Protocol: CTN0028

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SDTM 1.1/IG 3.1.1
ANNOTATION FOR CTN0028

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

DOMAIN: **SC**

CTN0028 : SYSTEM SCREENING (SCR)			
Protocol Number - NIDA-CTN-0028			
1.	NODE	SCTEST	A3	SCORRES
2.	Participant ID Please enter 3 numeric ID	USUBJID	A3	

DOMAIN: **DS**

CTN0028 : SYSTEM ENROLLMENT (Enr)			
Study Enrollment			
1. Participant ID USUBJID		A25	Please do not enter or modify data on this field NOTE: If this box does not have a value, please ensure that the Participant Id on the Screening Form has 3 numbers.

DSCAT=DISPOSITION EVENT

DSDECOD = SUBJECT ENROLLED

DSTERM=SUBJECT ENROLLED

SCCAT=DEMOGRAPHICS

DOMAIN: **DM, SC**

CTN0028 : 2801 - Demographics (DEM)

Patient Information

***WARNING: ANY CHANGES MADE TO THESE FIELDS BELOW WILL CHANGE THE IDENTIFICATION OF THIS SUBJECT - Changes that make these fields empty will not be acted upon and the prior values will remain for the purpose of identification. ***

1.	Patient Number	A15 siteno-NODE-Participant ID	USUBJID
2.	Node	A3	SCTEST/SCORRES
3.	Assessment Date	[99] ○ Req / Req / Req (2005-2008) (mm/dd/yyyy)	DMDTC
4.	Visit Number	[99] ○ xxx [98] ○ NA	VISITNUM/VISIT

Demographics

5.	1. Sex	[1] ○ 1 Male [2] ○ 2 Female [98] ○ NA	SEX
6.	2. Date of Birth	Req / Req / Req (1985-2008)	BRTHDTC
7.	3. Ethnicity		ETHNIC

3a. **[1]** ○ 1 Spanish origin, Hispanic or Latino

    3b.1. Mexican, Mexican-American, Chicano
      [0] ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
    3b.2. Puerto Rican
      [0] ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
    3b.3. Cuban
      [0] ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
    3b.4. Hispanic or Latino, other (specify)
      [0] ○ 0 No **[1]** ○ 1 Yes (specify) *[98]* ○ NA
      A50

[2] ○ 2 Not of Spanish origin, Hispanic or Latino
[98] ○ NA

4. Race

DM.RACE (if multiple then = 'MULTIPLE")

| 8. | 4.a American Indian or Alaskan Native | SCTEST | *[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA | SCORRES |
| 9. | 4.b Asian | | *[0]* ○ 0 No **[1]** ○ 1 Yes (If Yes) *[98]* ○ NA | |

    4.b.1 Asian-Indian
      [0] ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
    4.b.2 Chinese
      [0] ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
    4.b.3 Filipino
      [0] ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
    4.b.4 Japanese
      [0] ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
    4.b.5 Korean
      [0] ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
    4.b.6 Vietnamese
      [0] ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
    4.b.7 Asian, other
      [0] ○ 0 No **[1]** ○ 1 Yes (specify) *[98]* ○ NA
      A50

QNAM=AOTHERS
QLABEL=ASIAN OTHER TEXT
IDVAR=SCSEQ

| 10. | 4.c Black or African American | *[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA | SCTEST SCORRES |
| 11. | 4.d Native Hawaiian or Pacific Islander | *[0]* ○ 0 No **[1]** ○ 1 Yes (If Yes) *[98]* ○ NA | SCORRES |

SCTEST

    4.d.1 Native Hawaiian
      [0] ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
    4.d.2 Guamanian or Chamorro
      [0] ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
    4.d.3 Samoan
      [0] ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
    4.d.4 Native Hawaiian or Pacific Islander, other
      [0] ○ 0 No **[1]** ○ 1 Yes (specify) *[98]* ○ NA
      A50

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

DM.RACE (if multiple then = 'MULTIPLE")   DOMAIN: **DM, SC**

12.	4.e White		[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA	SCORRES
13.	4.f Race: Other	SCTEST	[0] ○ 0 No **[1]** ○ 1 Yes Other (specify) A50 [98] ○ NA	QNAM=OOTHERS QLABEL=ETHNICITY/RACE OTHER TEXT IDVAR=SCSEQ
14.	4.g Race: Participant chooses not to answer		[1] ○ 1 Yes [98] ○ NA	
15.	4.h Race: Unknown		[1] ○ 1 Yes [98] ○ NA	
5. Legal System Involvement				
16.	5a. Are you currently on Probation?	SCTEST	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA	SCORRES
17.	5b. Are you court ordered to substance abuse treatment?		[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA	

SCTEST   SCORRES

QSCAT=DSM-IV ADHD CHECKLIST   **DOMAIN: QS**

CTN0028 : 2803 - DSM-IV ADHD CHECKLIST (DSM) - Repeating Form

#	Assessment Date	Visit Number	Sequence Number	Respondent	Carelessness	Attention	Listen	Follow through	Organize	Tasks	Loses	Distractible	Forgetful	Squirm/Fidget	Stays seated	Runs/Climbs	Play/Work Quietly	On the Go	Talking	Answering	Waiting	Intrudes/in
1																						

QSDTC
VISITNUM/VISIT
QSSPID
QSTEST   **QSORRES**

1.	Assessment Date	Req ▾ / Req ▾ / Req ▾ (2005-2008) (mm/dd/yyyy)
2.	Visit Number	[99] ○ xxx [98] ○ NA
3.	Sequence Number	[99] ○ xx [98] ○ NA
4.	Respondent:	[1] ○ 1 Adolescent [2] ○ 2 Parent/Guardian [3] ○ 3 Adolescent and Parent/Guardian [98] ○ NA
5.	1. Carelessness	Pulldown List 1 ▾
6.	2. Difficulty sustaining attention in activities	Pulldown List 2 ▾
7.	3. Doesn't listen	Pulldown List 3 ▾
8.	4. No follow through	Pulldown List 4 ▾
9.	5. Can't organize	Pulldown List 5 ▾
10.	6. Avoids/dislikes tasks requiring sustained mental effort	Pulldown List 6 ▾
11.	7. Loses important items	Pulldown List 7 ▾
12.	8. Easily distractible	Pulldown List 8 ▾
13.	9. Forgetful in daily activities	Pulldown List 9 ▾
14.	10. Squirms and fidgets	Pulldown List 10 ▾
15.	11. Can't stay seated	Pulldown List 11 ▾
16.	12. Runs/climbs excessively	Pulldown List 12 ▾
17.	13. Can't play/work quietly	Pulldown List 13 ▾
18.	14. On the go, driven by a motor	Pulldown List 14 ▾
19.	15. Talks excessively	Pulldown List 15 ▾
20.	16. Blurts out answers	Pulldown List 16 ▾
21.	17. Can't wait for turn	Pulldown List 17 ▾
22.	18. Intrudes/interrupts others	Pulldown List 18 ▾
23.	Total Score (Screening/Baseline Only)	[99] ○ xx (2821-Study Eligibility Q-8) [98] ○ NA

QSCAT=K-SADS-E ADHD MODULE – INTERVIEW SUMMARY   DOMAIN: **QS/CO**

	CTN0028 : 2804- K-SADS-E ADHD Module - Interview Summary (KSA)				
1.	Assessment Date — QSDTC		Req / Req / Req (2005-2008) (mm/dd/yyyy)		
2.	Visit Number — VISITNUM/VISIT		[99] ○ xxx [98] ○ NA		
I. Inattention (6 or more of the following) QSSCAT = INATTENTION					
			Past	Cur	On Off
3.	1. Careless/Sloppy — QSTEST	QSORRES	Pulldown List 1	Pulldown List 2	xx xx
4.	2. Difficulty sustaining attention		Pulldown List 3	Pulldown List 4	xx xx
5.	3. Doesn't Listen		Pulldown List 5	Pulldown List 6	xx xx
6.	4. Difficulty Following Instructions		Pulldown List 7	Pulldown List 8	xx xx
7.	5. Difficulty Organizing Tasks/Activities		Pulldown List 9	Pulldown List 10	xx xx
8.	6. Difficulty With Sustained Mental Effort		Pulldown List 11	Pulldown List 12	xx xx
9.	7. Loses Things		Pulldown List 13	Pulldown List 14	xx xx
10.	8. Easily Distracted		Pulldown List 15	Pulldown List 16	xx xx
11.	9. Forgetful in Daily Activities		Pulldown List 17	Pulldown List 18	xx xx
12.*	Comments: Inattention Symptoms		A200 CO.COVAL IDVAR=QSSEQ		
II. Hyperactivity/Impulsivity (6 or more of the following) QSSCAT = HYPERACTIVITY/IMPULSIVITY					
			Past	Cur	On Off
13.	1. Fidgets/Squirms — QSTEST	QSORRES	Pulldown List 19	Pulldown List 20	xx xx
14.	2. Difficulty remaining seated		Pulldown List 21	Pulldown List 22	xx xx
15.	3. Runs/Climbs Excessively/Inappropriately		Pulldown List 23	Pulldown List 24	xx xx
16.	4. Difficulty Playing Quietly		Pulldown List 25	Pulldown List 26	xx xx
17.	5. "On the Go"/Driven by a motor		Pulldown List 27	Pulldown List 28	xx xx
18.	6. Talks Excessively		Pulldown List 29	Pulldown List 30	xx xx
19.	7. Blurts Out Answers		Pulldown List 31	Pulldown List 32	xx xx
20.	8. Difficulty Waiting Turn		Pulldown List 33	Pulldown List 34	xx xx
21.	9. Interrupts or Intrudes		Pulldown List 35	Pulldown List 36	xx xx
22.*	Comments: Hyperactivity/Impulsivity Symptoms		A200 CO.COVAL IDVAR=QSSEQ		
*	Item is not required				

QSCAT=K-SADS-E ADHD MODULE – INTERVIEW SUMMARY   DOMAIN: **QS**

	CTN0028 : 2804- K-SADS-E ADHD Module - Interview Summary continued (KSA2)		
1.	Assessment Date	QSDTC	Req ∨ / Req ∨ / Req ∨ (2005-2008) (mm/dd/yyyy)
2.	Visit Number	VISITNUM/VISIT	[99] ○ xxx [98] ○ NA

Additional Symptoms - For Parent Interview Only   QSSCAT = ADDITIONAL SYMPTOMS

QSTEST   QSORRES

		Past	Cur	On	Off
3.	1. Acts Before Thinking	Pulldown List 1 ∨	Pulldown List 2 ∨	xx	xx
4.	2. Shifts Activities Excessively	Pulldown List 3 ∨	Pulldown List 4 ∨	xx	xx
5.	3. Accidents	Pulldown List 5 ∨	Pulldown List 6 ∨	xx	xx
6.	4. Clumsy	Pulldown List 7 ∨	Pulldown List 8 ∨	xx	xx
7.	5a. Fights With Other Kids His/Her Age (more than most kids)	Pulldown List 9 ∨	Pulldown List 10 ∨	xx	xx
8.	5b. Get Rejected By Other Kids His/Her Age (more than most kids)	Pulldown List 11 ∨	Pulldown List 12 ∨	xx	xx
9.	6. Was Child Considered Hyperactive (By Anyone)?	Pulldown List 13 ∨	Pulldown List 14 ∨	xx	xx

Skip questions 7 and 8 if does not meet subthreshold...

		Past	Cur	On	Off
10.	7a. Attention Problem	Pulldown List 15 ∨	Pulldown List 16 ∨	xx	xx
11.	7b. Activity Problem	Pulldown List 17 ∨	Pulldown List 18 ∨	xx	xx
12.	7c. Both Equally Problematic	Pulldown List 19 ∨	Pulldown List 20 ∨	xx	xx
13.	8. Was he/she like this before age 7?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA			
14.	9. Academic achievement during 2nd to 5th grade, on average, was:	[1] ○ 1 Poor (Ds & Fs) [2] ○ 2 Fair (Cs & Ds) [3] ○ 3 Average (Bs & Cs) [4] ○ 4 Good (As & Bs) [98] ○ NA			

Skip question 10 if participant does not meet subthreshold (at least 3.5) or threshold (at least 6)
Cross-Situationality:

		Past	Cur	On	Off
15.	10a. Are these symptoms present at school?	Pulldown List 21 ∨	Pulldown List 22 ∨	xx	xx
16.	10b. Are these symptoms present at work or social settings?	Pulldown List 23 ∨	Pulldown List 24 ∨	xx	xx
17.	10c. Are these symptoms present at home?	Pulldown List 25 ∨	Pulldown List 26 ∨	xx	xx
18.	10d. Cross Situationality- Past:	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA			
19.*	Comments: Additional Symptoms, Cross-Situationality:	A200 CO.COVAL IDVAR=QSSEQ			

QSTEST   QSORRES

20.	Inattentive Type	Past Dx: Pulldown List 27 ∨ Onset: xx Current Dx: Pulldown List 28 ∨ #Cur Sxs: xxx.	
21.	Hyperactive/Impulsive Type	Past Dx: Pulldown List 29 ∨ Onset: xx Current Dx: Pulldown List 30 ∨ #Cur Sxs: xxx.	

* Item is not required

QSCAT=ASRS   DOMAIN: QS

	CTN0028 : 2805 - ASRS (ASR)	
1.	Assessment Date	Req ⌄ / Req ⌄ / Req ⌄ (2005-2008) (mm/dd/yyyy)
2.	Visit Number	[99] ○ xxx [98] ○ NA
	Please check the box that best describes how you have felt and conducted yourself over the past 6 months.	
3.	1. How often do you have trouble wrapping up the final details of a project, once the challenging parts have been done?	Pulldown List 1 ⌄
4.	2. How often do you have difficulty getting things in order when you have to do a task that requires organization?	Pulldown List 2 ⌄
5.	3. How often do you have problems remembering appointments or obligations?	Pulldown List 3 ⌄
6.	4. When you have a task that requires a lot of thought, how often do you avoid or delay getting started?	Pulldown List 4 ⌄
7.	5. How often do you fidget or squirm with your hands or your feet when you have to sit for a long time?	Pulldown List 5 ⌄
8.	6. How often do you feel overly active and compelled to do things, like you were driven by a motor?	Pulldown List 6 ⌄

QSDTC

VISITNUM/VISIT

QSTEST   QSORRES

CMCAT = 'PRIOR AND CONCOMITANT MEDICATIONS'   DOMAIN: CM

CTN0028 : 2810 - Prior And Concomitant Medications (PCM) - Repeating Form

#	Assessment Date	Visit Number	Sequence Number	Additional Meds	Medication Name	Purpose/Indication	Treatment of an AE?	Medication given for AE - Visit	Medication given for AE - Sequence	Quantity	Dosage	Dosage Form	Route of Administration	Frequency	Date Changed-Date	Visit on which AE Assessed	Date discontinued or changed Date	Visit discontinued or changed
1																		

1.	Assessment Date	[Req▼] / [Req▼] / [Req▼] (2005-2008) (mm/dd/yyyy) CMDTC
2.	Visit Number	[99] ○ xxx [98] ○ NA VISITNUM/VISIT
3.	Sequence Number	[99] ○ xx [98] ○ NA CMSEQ
4.	1. Has the participant taken any additional medications or changed dose/frequency of a medication since the last visit (or if this the baseline/screening visit, has the participant taken any medications in the past 30 days)?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA
5.	2. Medication Name (Generic name if possible; otherwise brand name)	[99] ○ A200 CMTRT [98] ○ NA
6.	3. Purpose/Indication:	[99] ○ A200 CMINDC [98] ○ NA
7.	4.a Is the drug being given for the treatment of an AE?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA
8.	4.b Visit#(AE)	[99] ○ xxx [98] ○ NA
9.	4.c Sequence#(AE)	[99] ○ xx [98] ○ NA
10.	5. Quantity per administration	[99] ○ xxxxxxxxxxxxxxx [98] ○ NA CMDOSE
11.	6. Dosage Units (If other, specify in 6.b).	a. Pulldown List 1 ▼ CMDOSU b. A50
12.	7. Dosage Form (If other, specify in 7.b).	a. Pulldown List 2 ▼ CMDOSFRM b. A50
13.	8. Route of Administration (If other, specify in 8.b).	a. Pulldown List 3 ▼ CMROUTE b. A50
14.	9. Frequency If Other Frequency, then specify.	a. Pulldown List 4 ▼ CMDOSFRQ b. A50
15.	10. Date added or dosage changed (Enter date medication was first taken or date when dosage or frequency was modified.)	[99] ○ [NReq▼] / [NReq▼] / [Req▼] (1995-2008) (mm/dd/yyyy) [98] ○ NA CMSTDTC
16.	11. If a medication is continuing at the same dose and frequency and the visit on which it is assessed is prior to the final visit of the study (visit 17 which occurs in week 20) then initial next to the visit number to indicate that the medication was assessed.	[99] ○ [1] □ 01 [2] □ 02 [3] □ 03 [4] □ 04 [5] □ 05 [6] □ 06 [7] □ 07 [8] □ 08 [9] □ 09 [10] □ 10 [11] □ 11 [12] □ 12 [13] □ 13 [14] □ 14 [15] □ 15 [16] □ 16 [17] □ 17 [98] ○ NA
17.	12. Date discontinued/changed/date of final study visit (If the dosage or frequency was modified, enter date of termination and re-enter as a new medication with the new dosage and/or frequency).	[99] ○ [Req▼] / [Req▼] / [Req▼] (2005-2008) (mm/dd/yyyy) [98] ○ NA CMENDTC
18.	13. Visit on which Date discontinued/changed/date of final study visit field (see 12) completed.	Pulldown List 5 ▼

There is only a record in the CM dataset when the answer to this question is 'Yes'

QNAM=TRTFORAE
QLABEL=DRUG GIVEN AS TREATMENT FOR AE
IDVAR=CMSEQ

QNAM=CMAEVIS
QLABEL=RELATED AE VISIT NUMBER
IDVAR=CMSEQ

QNAM=CMAEREF
QLABEL=RELATED AE FORM SEQUENCE NUMBER
IDVAR=CMSEQ

QNAM=CMCONTV
QLABEL=VISITS WHERE MED WAS ASSESSED/CONTINUED
IDVAR=CMSEQ

QNAM=VISITNO
QLABEL=VISIT THAT DRUG WAS DISCONTINUED OR CHAN
IDVAR=CMSEQ

DOMAIN: MH

	CTN0028 : 2815 - Medical History (MDH)	
1.	Assessment Date *MHDTC*	Req ▾ / Req ▾ / Req ▾ (2005-2008) (mm/dd/yyyy)
2.	Visit Number *VISIT / VISITNUM*	[99] ○ xxx [98] ○ NA
	Medical History *MHCAT=MEDICAL HISTORY*	*QNAM=MHSPEC*

MHOCCUR

MHTERM

QNAM=MHPRES
QLABEL=CONDITION PRESENT CURRENTLY
IDVAR=MHSEQ

QNAM=MHSPEC
QLABEL=MEDICAL HISTORY SPECIFY
IDVAR=MHSEQ

QNAM=MHEXCL
QLABEL=CONDITION EXCLUDES PARTICIPANT
IDVAR=MHSEQ

3.	1. Asthma	[0] ○ 0 No [1] ○ 1 Yes Specify A200 Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA [9] ○ 9 Unknown [98] ○ NA
4.	2. Cardiovascular	[0] ○ 0 No [1] ○ 1 Yes Specify A200 Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA [9] ○ 9 Unknown [98] ○ NA
5.	3. Dermatologic	[0] ○ 0 No [1] ○ 1 Yes Specify A200 Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA [9] ○ 9 Unknown [98] ○ NA
6.	4. Drug Allergies	[0] ○ 0 No [1] ○ 1 Yes Specify A200 Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA [9] ○ 9 Unknown [98] ○ NA
7.	5. Endocrine	[0] ○ 0 No [1] ○ 1 Yes Specify A200 Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA [9] ○ 9 Unknown [98] ○ NA
8.	6. Gastrointestinal	[0] ○ 0 No [1] ○ 1 Yes Specify A200 Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA [9] ○ 9 Unknown [98] ○ NA
9.	7. Genitourinary	[0] ○ 0 No [1] ○ 1 Yes Specify A200 Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA

This page is annotated in identical fashion to the first MH page.

DOMAIN: MH

		[9] ○ 9 Unknown [98] ○ NA
10.	8. Head Injury	[0] ○ 0 No [1] ○ 1 Yes Specify | A200 | Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA [9] ○ 9 Unknown [98] ○ NA
11.	9. HEENT	[0] ○ 0 No [1] ○ 1 Yes Specify | A200 | Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA [9] ○ 9 Unknown [98] ○ NA
12.	10. Hematologic	[0] ○ 0 No [1] ○ 1 Yes Specify | A200 | Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA [9] ○ 9 Unknown [98] ○ NA
13.	11. Hepatic	[0] ○ 0 No [1] ○ 1 Yes Specify | A200 | Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA [9] ○ 9 Unknown [98] ○ NA
14.	12. Infectious Disease	[0] ○ 0 No [1] ○ 1 Yes Specify | A200 | Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA [9] ○ 9 Unknown [98] ○ NA
15.	13. Metabolic	[0] ○ 0 No [1] ○ 1 Yes Specify | A200 | Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA [9] ○ 9 Unknown [98] ○ NA
16.	14. Musculoskeletal	[0] ○ 0 No [1] ○ 1 Yes Specify | A200 | Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA [9] ○ 9 Unknown [98] ○ NA
17.	15. Other Allergies	[0] ○ 0 No

This page is annotated in identical fashion to the first MH page.

DOMAIN: MH

		[1] ○ 1 Yes
		Specify
		A200
		Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
		Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
		[9] ○ 9 Unknown
		[98] ○ NA
18.	16. Pulmonary	[0] ○ 0 No
		[1] ○ 1 Yes
		Specify
		A200
		Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
		Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
		[9] ○ 9 Unknown
		[98] ○ NA
19.	17. Renal	[0] ○ 0 No
		[1] ○ 1 Yes
		Specify
		A200
		Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
		Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
		[9] ○ 9 Unknown
		[98] ○ NA
20.	18. Reproductive system	[0] ○ 0 No
		[1] ○ 1 Yes
		Specify
		A200
		Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
		Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
		[9] ○ 9 Unknown
		[98] ○ NA

Psychiatric/Neurological History   MHCAT=PSYCHIATRIC/NEUROLOGICAL HISTORY

21.	19. Anxiety or Panic Disorder	[0] ○ 0 No
		[1] ○ 1 Yes
		Specify
		A200
		Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
		Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
		[9] ○ 9 Unknown
		[98] ○ NA
22.	20. Attention Deficit Hyperactivity Disorder	[0] ○ 0 No
		[1] ○ 1 Yes
		Specify
		A200
		Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
		Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
		[9] ○ 9 Unknown
		[98] ○ NA
23.	21. Bipolar Disorder	[0] ○ 0 No
		[1] ○ 1 Yes
		Specify
		A200
		Condition Present Currently? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
		Condition Excludes Participant? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
		[9] ○ 9 Unknown
		[98] ○ NA
24.	22. Clinically Significant Neurological Damage	[0] ○ 0 No
		[1] ○ 1 Yes
		Specify
		A200

This page is annotated in identical fashion to the first MH page.

DOMAIN: MH

		Condition Present Currently? *[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
		Condition Excludes Participant? *[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
		[9] ○ 9 Unknown
		[98] ○ NA
25.	23. Epilepsy or Seizure Disorder	*[0]* ○ 0 No
		[1] ○ 1 Yes
		Specify
		A200
		Condition Present Currently? *[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
		Condition Excludes Participant? *[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
		[9] ○ 9 Unknown
		[98] ○ NA
26.	24. Major Depressive Disorder	*[0]* ○ 0 No
		[1] ○ 1 Yes
		Specify
		A200
		Condition Present Currently? *[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
		Condition Excludes Participant? *[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
		[9] ○ 9 Unknown
		[98] ○ NA
27.	25. Schizophrenia	*[0]* ○ 0 No
		[1] ○ 1 Yes
		Specify
		A200
		Condition Present Currently? *[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
		Condition Excludes Participant? *[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
		[9] ○ 9 Unknown
		[98] ○ NA
28.	26. Tourette's Syndrome	*[0]* ○ 0 No
		[1] ○ 1 Yes
		Specify
		A200
		Condition Present Currently? *[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
		Condition Excludes Participant? *[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
		[9] ○ 9 Unknown
		[98] ○ NA
29.	27. Suicidal Ideation	*[0]* ○ 0 No
		[1] ○ 1 Yes
		Specify
		A200
		Condition Present Currently? *[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
		Condition Excludes Participant? *[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
		[9] ○ 9 Unknown
		[98] ○ NA
30.	28. Suicidal Behavior	*[0]* ○ 0 No
		[1] ○ 1 Yes
		Specify
		A200
		Condition Present Currently? *[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
		Condition Excludes Participant? *[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
		[9] ○ 9 Unknown
		[98] ○ NA
31.	29. Homicidal Ideation	*[0]* ○ 0 No
		[1] ○ 1 Yes
		Specify
		A200
		Condition Present Currently? *[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
		Condition Excludes Participant? *[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA

DOMAIN: MH

		[9] ○ 9 Unknown [98] ○ NA

QNAM=MHSPEC
QLABEL=MEDICAL HISTORY SPECIFY
IDVAR=MHSEQ

32.	30. Homicidal Behavior	MHOCCUR	[0] ○ 0 No [1] ○ 1 Yes

MHTERM

QNAM=MHPRES
QLABEL=CONDITION PRESENT CURRENTLY
IDVAR=MHSEQ

Specify
A200
Condition Present Currently? [0] ○ 0 No   [1] ○ 1 Yes   [98] ○ NA
Condition Excludes Participant? [0] ○ 0 No   [1] ○ 1 Yes   [98] ○ NA

[9] ○ 9 Unknown
[98] ○ NA

33.	31. Violent Behavior	[0] ○ 0 No [1] ○ 1 Yes

QNAM=MHEXCL
QLABEL=CONDITION EXCLUDES PARTICIPANT
IDVAR=MHSEQ

Specify
A200
Condition Present Currently? [0] ○ 0 No   [1] ○ 1 Yes   [98] ○ NA
Condition Excludes Participant? [0] ○ 0 No   [1] ○ 1 Yes   [98] ○ NA

[9] ○ 9 Unknown
[98] ○ NA

34.	32. Psychotic Episodes	[0] ○ 0 No [1] ○ 1 Yes

Specify
A200
Condition Present Currently? [0] ○ 0 No   [1] ○ 1 Yes   [98] ○ NA
Condition Excludes Participant? [0] ○ 0 No   [1] ○ 1 Yes   [98] ○ NA

[9] ○ 9 Unknown
[98] ○ NA

35.	33. Tic Disorder	[0] ○ 0 No [1] ○ 1 Yes

Specify
A200
Condition Present Currently? [0] ○ 0 No   [1] ○ 1 Yes   [98] ○ NA
Condition Excludes Participant? [0] ○ 0 No   [1] ○ 1 Yes   [98] ○ NA

[9] ○ 9 Unknown
[98] ○ NA

Indicate other relevant medical history	MHCAT=OTHER RELEVANT MEDICAL HISTORY	

36.	34. Other 1	Indicate other relevant medical history A200

MHTERM

Specify the medical problem
A200
Condition Present Currently? [0] ○ 0 No   [1] ○ 1 Yes
Condition Excludes Participant? [0] ○ 0 No   [1] ○ 1 Yes

37.	35. Other 2	Indicate other relevant medical history A200

MHTERM

Specify the medical problem
A200
Condition Present Currently? [0] ○ 0 No   [1] ○ 1 Yes
Condition Excludes Participant? [0] ○ 0 No   [1] ○ 1 Yes

Surgical History	MHCAT=SURGICAL HISTORY	

38.	36. Has the subject had any major surgery? There is only a record in this MH dataset for surgery when the answer to this question is 'Yes'	[0] ○ 0 No [1] ○ 1 Yes [9] ○ 9 Unknown [98] ○ NA
	Type of Surgery	Surgery Date
39.		

QNAM=MHSPEC
QLABEL=MEDICAL HISTORY SPECIFY
IDVAR=MHSEQ

Procedures and Dates Entry		
39.a	Type of Surgery	A255
		MHTERM
39.b	Surgery Date	[99] ○ NReq / NReq / NReq (1950-2008) [9] ○ 9 Unknown MHSTDTC

QSCAT=CHILDRENS GLOBAL ASSESSMENT FORM   DOMAIN: **QS**

CTN0028 : 2816 - Childrens Global Assessment Form (CGA)		
1.	Assessment Date QSDTC	NReq ⌄ / NReq ⌄ / NReq ⌄ (2005-2008) (mm/dd/yyyy)
2.	Visit Number VISITNUM/VISIT	[99] ◯ xxx [98] ◯ NA
3.	1. Global Assessment Score QSTEST	[99] ◯ xxx [98] ◯ NA QSORRES

DOMAIN: LB, CO

LBCAT=DRUG SCREEN

CTN0028 : 2806 - Urine Drug Screen (UDS)	
1. Assessment Date — LBDTC	Req ▾ / Req ▾ / Req ▾ (2005-2008) (mm/dd/yyyy)
2. Visit Number — VISIT / VISITNUM	[99] ○ xxx [98] ○ NA

Section I: Urine Collection

| 3. 1. Was a urine sample obtained? — LBSTAT / LBREASND | (If Yes, skip to question 2)
[0] ○ 0 No 1.a Why was a urine sample not obtained?
   [1] ○ 1 Participant reported being unable to provide sample
   [2] ○ 2 Participant refused to provide sample
   [3] ○ 3 Study Staff Error
   [4] ○ 4 Other (SPECIFY):
       A200
   [98] ○ NA
[1] ○ 1 Yes
[98] ○ NA |

QNAM=LBSUPER
QLABEL=URINE COLLECTION SUPERVISED
IDVAR=LBSEQ

QNAM=LBADULT
QLABEL=ADULTERANT TEST INDICATES TEST VALID
IDVAR=LBSEQ

4. 2. Was urine collection observed?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5. 3. Urine temperature within expected range (between 90 and 99 degrees Fahrenheit)?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA

Section II: Urine Drug Screen Results

| 6. 4. Does the adulterant test indicate that the test was valid? | [0] ○ 0 No
[1] ○ 1 Yes |

LBTEST / LBTESTCD

LBORRES

QNAM=LBTEMP
QLABEL=URINE TEMP WITHIN EXPECTED RANGE
IDVAR=LBSEQ

5. Amphetamine [1] ○ 1 Negative [2] ○ 2 Positive [3] ○ 3 Unknown [98] ○ NA
6. Barbiturates [1] ○ 1 Negative [2] ○ 2 Positive [3] ○ 3 Unknown [98] ○ NA
7. Benzodiazepines [1] ○ 1 Negative [2] ○ 2 Positive [3] ○ 3 Unknown [98] ○ NA
8. Cocaine [1] ○ 1 Negative [2] ○ 2 Positive [3] ○ 3 Unknown [98] ○ NA
9. Methamphetamine [1] ○ 1 Negative [2] ○ 2 Positive [3] ○ 3 Unknown [98] ○ NA
10. Morphine (opiates) [1] ○ 1 Negative [2] ○ 2 Positive [3] ○ 3 Unknown [98] ○ NA
11. THC (marijuana) [1] ○ 1 Negative [2] ○ 2 Positive [3] ○ 3 Unknown [98] ○ NA
[98] ○ NA

| 7.* Comments: | A200 |

CO.COVAL
IDVAR=LBSEQ

* Item is not required

LBCAT=URINALYSIS

DOMAIN: LB, CO

CTN0028 : 2807 - Urinalysis (URI) - Repeating Form

#	Assessment Date	Visit Number	Sequence Number	Specific gravity	Specific Gravity Comments	pH	pH Comments	Glucose	Glucose Comments	Protein	Protein Comments	Ketones	Ketones Comments	Blood	Blood Comments	Leukocytes	Leukocytes Comments	Nitrite	Nitrite Comments	Bilirubin	Bilirubin Comments	Urobilinogen
1																						

1.	Assessment Date	**LBDTC**	Req ∨ / Req ∨ / Req ∨ (2005-2008) (mm/dd/yyyy)
2.	Visit Number	**VISIT / VISITNUM**	[99] ○ xxx [98] ○ NA
3.	Sequence Number	**LBSPID**	[99] ○ xx [98] ○ NA
4.	1a. Specific gravity		Pulldown List 1 ∨
5.	1b. Specific Gravity Comments *(required for abnormal values)*	**LBTEST** **LBORRES /LBSTAT**	[99] ○ Comments A200 [98] ○ NA
6.	2a. pH		Pulldown List 2 ∨
7.	2b. pH Comments *(required for abnormal values)*	**CO.COVAL IDVAR=LBSEQ**	[99] ○ Comments A200 [98] ○ NA
8.	3a. Glucose		Pulldown List 3 ∨
9.	3b. Glucose Comments *(required for abnormal values)*		[99] ○ Comments A200 [98] ○ NA
10.	4a. Protein		Pulldown List 4 ∨
11.	4b. Protein Comments *(required for abnormal values)*		[99] ○ Comments A200 [98] ○ NA
12.	5a. Ketones		Pulldown List 5 ∨
13.	5b. Ketones Comments *(required for abnormal values)*		[99] ○ Comments A200 [98] ○ NA
14.	6a. Blood		Pulldown List 6 ∨
15.	6b. Blood Comments *(required for abnormal values)*		[99] ○ Comments A200 [98] ○ NA
16.	7a. Leukocytes		Pulldown List 7 ∨
17.	7b. Leukocytes Comments *(required for abnormal values)*		[99] ○ Comments A200 [98] ○ NA
18.	8a. Nitrite		Pulldown List 8 ∨
19.	8b. Nitrite Comments *(required for abnormal values)*		[99] ○ Comments A200 [98] ○ NA
20.	9a. Bilirubin		Pulldown List 9 ∨
21.	9b. Bilirubin Comments *(required for abnormal values)*		[99] ○ A200 [98] ○ NA
22.	10a. Urobilinogen		Pulldown List 10 ∨
23.	10b. Urobilinogen Comments *(required for abnormal values)*		[99] ○ A200 [98] ○ NA

LBCAT=HEMATOLOGY

DOMAIN: LB, CO

#	Assessment Date	Visit Number	Seq #	Hemoglobin	Hematocrit	RBC	Platelet Count	WBC	Neutrophils	Lymphocytes	Monocytes	Eosinophils	Basophils
1													

1.	Assessment Date	**LBDTC**	Req ▾ / Req ▾ / Req ▾ (2005-2008) (mm/dd/yyyy)
2.	Visit Number	**VISIT / VISITNUM**	[99] ○ xxx [98] ○ NA
3.	Sequence Number	**LBSPID**	[99] ○ xx [98] ○ NA
4.	1. Hemoglobin **LBTEST** **LBORRES**		xxxxxx.x g/dl Other Unit A10 Assessment Pulldown List 1 ▾ Comments A200 **CO.COVAL IDVAR=LBSEQ**
	LBORRESU **LBSTAT/LBNRIND**		
5.	2. Hematocrit		xxxxxx.x % Other Unit A10 Assessment Pulldown List 2 ▾ Comments A200
6.	3. RBC		xxxxxx.x million/mm³ Other Unit A10 Assessment Pulldown List 3 ▾ Comments A200
7.	4. Platelet Count		xxxxxxxx thousand/mm³ Other Unit A10 Assessment Pulldown List 4 ▾ Comments A200
8.	5. WBC		xxxxxx.x thousand/mm³ Other Unit A10 Assessment Pulldown List 5 ▾ Comments A200
9.	a. Neutrophils		xxxxxx.x % Other Unit A10 Assessment Pulldown List 6 ▾ Comments A200
10.	b. Lymphocytes		xxxxxx.x % Other Unit A10 Assessment Pulldown List 7 ▾ Comments A200
11.	c. Monocytes		xxxxxx.x % Other Unit A10 Assessment Pulldown List 8 ▾ Comments A200
12.	d. Eosinophils		xxxxxx.x % Other Unit A10 Assessment Pulldown List 9 ▾ Comments A200
13.	e. Basophils		xxxxxx.x % Other Unit A10 Assessment Pulldown List 10 ▾ Comments A200

RPCAT=PREGNANCY TEST

DOMAIN: RP, CO

	CTN0028 : 2809 - Pregnancy and Birth Control Assessment (PBC)	
1.	Assessment Date	Req / Req / Req (2005-2008) (mm/dd/yyyy) **RPDTC**
2.	Visit Number	[99] ○ xxx [98] ○ NA **VISIT / VISITNUM**
	Pregnancy Test	
3.	1. Was a pregnancy test performed? **RPTEST/RPTESTCD**	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA **RPORRES** 2. If yes, what type of test was completed? [1] ○ 1 Urine [2] ○ 2 Serum [98] ○ NA
4.	3. Date of pregnancy test	[99] ○ Req/Unk / Req/Unk / Req/Unk (2005-2008) (mm/dd/yyyy) [98] ○ NA
5.	4. Pregnancy test result	[1] ○ 1 Negative [2] ○ 2 Positive [98] ○ NA
	Breastfeeding - Complete only during Baseline/Screening	
6.	5. Is the participant breastfeeding?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
	Birth Control Method - Complete on during Baseline/Screening	
7.	6a. Does the participant agree to use an acceptable method of birth control?	[0] ○ 0 No [1] ○ 1 Yes (If Yes, Indicate all methods of birth control the participant agrees to use:) [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA 6b. Abstinence [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA 6c. Barrier [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA 6d. IUD [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA 6e. Levonorgestrel Implant [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA 6f. Medroxyprogesterone Acetate Injection [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA 6g. Oral Contraceptives [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA 6h. Patch [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA 6i. Surgical Sterilization [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA 6j. Other 6k. Specify A100 [98] ○ NA
8.*	7. Comments:	A200
*	Item is not required	

CO.COVAL
IDVAR=VISITNUM

LBCAT=BLOOD CHEMISTRY

DOMAIN: LB, CO

CTN0028 : 2811 Blood Chemistry (BLC) - Repeating Form

#	Assessment Date	Visit Number	Seq #	LDH value	CPK value	ALP value	BUN	CO^2	Chloride	Creatinine	GGT	Glucose	Potassium	SGOT/AST	SGPT/ALT	Sodium	Total Protein	Total Bilirubin	Comments for abnormal values
1																			

1.	Assessment Date	**LBDTC**	Req ⌄ / Req ⌄ / Req ⌄ (2005-2008) (mm/dd/yyyy)
2.	Visit Number	**VISIT / VISITNUM**	[99] ○ xxx [98] ○ NA
3.	Sequence Number	**LBSPID**	[99] ○ xx [98] ○ NA
4.	1. Lactate Dehydrogenase value	**LBTEST** **LBORRES**	xxxxxx.x U/L Other Unit Pulldown List 1 ⌄ **LBSTAT/LBNRIND** **LBORRESU** A10
5.	2. Creatinine Phosphokinase (CPK)		xxxxxx.x U/L A10 Pulldown List 2 ⌄
6.	3. Alkaline Phosphatase (ALP)		xxxxxx.x U/L A10 Pulldown List 3 ⌄
7.	4. Blood Urea Nitrogen (BUN)		xxxxxx.x mg/dL A10 Pulldown List 4 ⌄
8.	5. CO^2		xxxxxx.x mEq/L A10 Pulldown List 5 ⌄
9.	6. Chloride		xxxxxx.x mEq/L A10 Pulldown List 6 ⌄
10.	7. Creatinine		xxxxxx.x mg/dL A10 Pulldown List 7 ⌄
11.	8. Gamma Glutamyl-transpeptidase (GGT)		xxxxxx.x U/L A10 Pulldown List 8 ⌄
12.	9. Glucose		xxxxxx.x mg/dL A10 Pulldown List 9 ⌄
13.	10. Potassium		xxxxxx.x mEq/L A10 Pulldown List 10 ⌄
14.	11. SGOT/AST		xxxxxx.x U/L A10 Pulldown List 11 ⌄
15.	12. SGPT/ALT		xxxxxx.x U/L A10 Pulldown List 12 ⌄
16.	13. Sodium		xxxxxx.x mEq/L A10 Pulldown List 13 ⌄
17.	14. Total Protein		xxxxxx.x g/dL A10 Pulldown List 14 ⌄
18.	15. Total Bilirubin		xxxxxx.x mg/dL A10 Pulldown List 15 ⌄
19.*	16. Provide comments for any abnormal value(s):		A200 **CO.COVAL**

* Item is not required

IDVAR=LBSEQ

DOMAIN: SU

	CTN0028 : 2812 - TLFB - Pre-Treatment (TLF)											
1.	Assessment Date	NReq ▾ / NReq ▾ / NReq ▾ (2005-2008) (mm/dd/yyyy) SUDTC										
2.	Visit Number	**[99]** ○ xxx **[98]** ○ NA VISIT / VISITNUM										
3.	1. Primary Drug	Pulldown List 1 ▾ Specify other A50 ⎸										

DATA NOT ENTERED

	Day	Date	Alcohol standard drinks	Marijuana joints	Cigarettes cpd	Other Tobac	OTC Meds	Cocaine	Cocaine Route	Amphetamine	Amp Rou
4.											

QNAM=PRIMDRUG
QLABEL=PRIMARY DRUG
IDVAR=SUSTDTC

QNAM=OTHPRIM
QLABEL=OTHER PRIMARY DRUG
IDVAR=SUSTDTC

SUGRPID
SUSTDTC
SUTRT
SUOCCUR
SUDOSE / SUDOSU
SUROUTE

4.a	Day	Pulldown List 2 ▾
4.b	2. Date	**[99]** ○ Req ▾ / Req ▾ / Req ▾ (2005-2008) **[98]** ○ NA
4.c	3. Alcohol	**[99]** ○ # Stnd Drinks xxx **[98]** ○ NA
4.d	4. Marijuana	**[99]** ○ # jnts xxx **[98]** ○ NA
4.e	5. Cigarettes	**[99]** ○ # cpd xxx **[98]** ○ NA
4.f	6. Other Tobac	*[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
4.g	7. OTC Meds	*[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
4.h	8. Cocaine	*[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
4.i	Cocaine Route	Pulldown List 3 ▾
4.j	9. Amphetamine	*[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
4.k	Amphetamine Route	Pulldown List 3 ▾
4.l	10. Methamphetamine	*[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
4.m	Methamphetamine Route	Pulldown List 3 ▾
4.n	11. Opiates	*[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
4.o	Opiates Route	Pulldown List 3 ▾
4.p	12. Sedatives	*[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
4.q	13. Hallucinogens	*[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
4.r	14. Club Drugs	*[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
4.s	15. Inhalant	*[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
4.t	Inhalant Specify	**[99]** ○ A20 **[98]** ○ NA
4.u	16. Other	*[0]* ○ 0 No *[1]* ○ 1 Yes *[98]* ○ NA
4.v	Other Specify	**[99]** ○ A20 **[98]** ○ NA
4.w	Other Route	Pulldown List 3 ▾

SUROUTE (Cocaine, Amphetamine, Methamphetamine, Opiates)
SUTRT
SUROUTE (Other Route)

5.	17. Is there a discrepancy between the self-report and today's urine toxicology results?	*[98]* ○ NA *[0]* ○ 0 No **[1]** ○ 1 Yes

17a. If yes, please indicate for which drug(s)

Amphetamine	Barbiturates	Benzos	Cocaine	Methamphetamine	Morphine (opiates)	THC (marijuana)
[0] ○ 0 No	*[0]* ○ 0 No	*[0]* ○ 0 No	*[0]* ○ 0 No	*[0]* ○ 0 No	*[0]* ○ 0 No	*[0]* ○ 0 No
[1] ○ 1 Yes	*[1]* ○ 1 Yes	*[1]* ○ 1 Yes	*[1]* ○ 1 Yes	*[1]* ○ 1 Yes	*[1]* ○ 1 Yes	*[1]* ○ 1 Yes
[98] ○ NA	*[98]* ○ NA	*[98]* ○ NA	*[98]* ○ NA	*[98]* ○ NA	*[98]* ○ NA	*[98]* ○ NA

QNAM=SUDISC
QLABEL=DISCREPANCY BETWEEN SELF REPORT AND TOX
IDVAR=SUSTDTC

QNAM=(AMPHET, BARBIT, BENZO, COCAINE, METHAM, MORPHINE, THC
QLABEL=URINE TEST DISCREPANCY: drug name
IDVAR=SUSTDTC

DOMAIN: PE

	CTN0028 : 2813 - Physical Exam (PEX)		
1.	Assessment Date	PEDTC	Req ˅ / Req ˅ / Req ˅ (2005-2008) (mm/dd/yyyy)
2.	Visit Number	VISIT / VISITNUM	[99] ○ xxx [98] ○ NA
3.	1. General Appearance	PETEST PEORRES	Evaluation **Comments for Abnormal Results** CO.COVAL IDVAR=PESEQ Pulldown List 1 ˅ A200
4.	2. Head/Neck		Pulldown List 2 ˅ A200
5.	3. EENT		Pulldown List 3 ˅ A200
6.	4. Cardiovascular and Pulse		Pulldown List 4 ˅ A200
7.	5. Lymph Nodes		Pulldown List 5 ˅ A200
8.	6. Respiratory		Pulldown List 6 ˅ A200
9.	7. Musculoskeletal		Pulldown List 7 ˅ A200
10.	8. Gastrointestinal and Abdomen		Pulldown List 8 ˅ A200
11.	9. Extremities		Pulldown List 9 ˅ A200
12.	10. Neurological		Pulldown List 10 ˅ A200
13.	11. Skin		Pulldown List 11 ˅ A200
14.*	12. Other Evaluation		Specify: A200 Pulldown List 12 ˅ A200 CO.COVAL IDVAR=PESEQ
*	Item is not required		

QNAM=OTHSPEC
QLABEL=OTHER EVALUATION SPECIFY
IDVAR=PESEQ

CTN0028 : 2814 - Vital Signs (VSF)   **DOMAIN: VS, CO**

1.	Assessment Date	VSDTC	[Req ▼] / [Req ▼] / [Req ▼] (2005-2008) (mm/dd/yyyy)
2.	Visit Number	VISIT/VISITNUM	[99] ○ xxx [98] ○ NA

Reading 1 VSCAT=READING 1   VSORRES/VSORRESU

3.	A. Pulse (beats per minute)	VSTEST / VSTESTCD	[99] ○ xxx [98] ○ NA
4.	B. Systolic Blood Pressure		[99] ○ Systolic xxx [98] ○ NA
5.	C. Diastolic Blood Pressure		[99] ○ Diastolic xxx [98] ○ NA
6.	D. Weight (Scrn, wks 4, 8, 12, 16)		[99] ○ xxx lbs [98] ○ NA
7.	E. Height (Scrn)		[99] ○ xxx in [98] ○ NA

Reading 2 VSCAT=READING 2

If the systolic blood pressure for the first reading is >140 or <90 OR the diastolic blood pressure for the first reading is >90 or <60 then wait three minutes and then repeat the assessment.

8.	B. Systolic Blood Pressure	[99] ○ Systolic xxx [98] ○ NA
9.	C. Diastolic Blood Pressure	[99] ○ Diastolic xxx [98] ○ NA

Reading 3 VSCAT=READING 3

If two blood pressure readings were completed then average the systolic readings and average the diastolic readings and record the averages in the appropriate fields below.

10.	Systolic average of 1 and 2	[99] ○ Systolic xxx [98] ○ NA
11.	Diastolic average of 1 and 2	[99] ○ Diastolic xxx [98] ○ NA
12.*	Comments:	A200 CO.COVAL

* Item is not required

IDVAR=VISITNUM

QSCAT=DSM IV DIAGNOSTIC SCALE   **DOMAIN: QS**

CTN0028 : 2817 - DSM IV Diagnostic Scale (DDS)	
1.	Assessment Date **QSDTC**	NReq ⌄ / NReq ⌄ / NReq ⌄ (2005-2008) (mm/dd/yyyy)
2.	Visit Number **VISITNUM/VISIT**	[99] ○ xxx [98] ○ NA

I. Summary of CIDI QSSCAT = SUMMARY OF CIDI

3.	1. Does the participant meet DSM-IV criteria for any current substance abuse or dependence disorders?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA **QSORRES**
	DSM-IV Code if currently meets criteria **QSTEST**	DSM-IV Diagnosis if currently meets criteria
4.		

2. If Yes, list the substance abuse/dependence disorder(s) for which the participant currently meets criteria Entry

4.a*	DSM IV Code if currently meets criteria	xxxxxxx.
4.b*	DSM IV Diagnosis if currently meets criteria	A200
5.	3. Does the participant meet DSM-IV criteria for a lifetime diagnosis for any substance abuse/dependence disorder for which he or she does not meet criteria?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
	DSM-IV Code if meets lifetime criteria	DSM-IV Diagnosis if meets lifetime criteria
6.		

4. If Yes, list the disorder(s) for which the participant meets lifetime criteria Entry

6.a*	DSM IV Code if meets lifetime criteria	xxxxxxx.
6.b*	Lifetime DSM IV Diagnosis if meets lifetime criteria	A200

II. Summary of K-SADS QSSCAT = SUMMARY OF K-SADS

7.	5. Does the participant currently meet DSM-IV criteria for any non-substance psychiatric disorders(other than ADHD)?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
	DSM-IV Code non-substance psychiatric disorder	DSM-IV Diagnosis non-substance psychiatric disorder
8.		

6. If Yes, list the disorder(s) for which the participant currently meets criteria Entry

8.a*	DSM-IV Code non-substance psychiatric disorder	xxxxxxx.
8.b*	DSM-IV Diagnosis non-substance psychiatric disorder	A200
9.	7. Does the participant meet DSM-IV criteria for a lifetime diagnosis for any non-substance psychiatric disorder for which he or she does not meet current criteria(other than ADHD)?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
	DSM-IV Code lifetime criteria for non-substance psychiatric disorder	DSM-IV Diagnosis lifetime criteria for non-substance psychiatric disorder
10.		

8. If Yes, list the disorder(s) for which the participant meets lifetime criteria Entry

10.a*	DSM-IV Code lifetime criteria for non-substance psychiatric disorder	xxxxxxx.
10.b*	DSM-IV Diagnosis lifetime criteria for non-substance psychiatric disorder	A200

* Item is not required

QSCAT=CHILD HEALTH QUESTIONNAIRE   DOMAIN: **QS**

CTN0028 : 2818 - Child Health Questionnaire (CHQ1)

1.	Assessment Date QSDTC	Req ⌄ / Req ⌄ / Req ⌄ (2005-2008) (mm/dd/yyyy)
2.	Visit Number VISITNUM/VISIT	[99] ○ xxx [98] ○ NA

SECTION #1: YOUR GLOBAL HEALTH   QSSCAT = YOUR GLOBAL HEALTH

3.	1.1. In general, would you say your health is: QSTEST	Pulldown List 1 ⌄	QSORRES

SECTION #2: YOUR GLOBAL HEALTH

The following questions ask about physical activities you might do during a day.

2.1. During the past 4 weeks, has it been difficult for you to do the following activities due to health problems?

4.	a. Do things that take a lot of energy, such as playing soccer, running or hiking?	Pulldown List 2 ⌄
5.	b. Do things that take some energy such as riding a bike or skating?	Pulldown List 3 ⌄
6.	c. Walk several blocks or climb several flights of stairs?	Pulldown List 4 ⌄
7.	d. Get around your school neighborhood, or playground?	Pulldown List 5 ⌄
8.	e. Walk one block or climb one flight of stairs?	Pulldown List 6 ⌄
9.	f. Do your tasks around the house?	Pulldown List 7 ⌄
10.	g. Bend, lift, or stoop?	Pulldown List 8 ⌄
11.	h. Eat, dress, bath, or go to the toilet by yourself?	Pulldown List 9 ⌄
12.	i. Get in and out of bed?	Pulldown List 10 ⌄

SECTION #3: YOUR EVERYDAY ACTIVITIES   QSSCAT = YOUR EVERYDAY ACTIVITIES

3.1. During the past 4 weeks, has it been difficult to do your school work or usual activities with friends because of problems like FEELING SAD OR WORRIED?

13.	a. Do certian kinds of schoolwork or activities with friends?	Pulldown List 11 ⌄
14.	b. Spend the usual amount of time on schoolwork or activities with friends?	Pulldown List 12 ⌄
15.	c. Get schoolwork done at all or do any activities with friends?	Pulldown List 13 ⌄

3.2. During the past 4 weeks, has it been difficult to do your school work or usual activities with friends because of problems with your BEHAVIOR?

16.	a. Do certain kinds of schoolwork or activities with friends?	Pulldown List 14 ⌄
17.	b. Spend the usual amount of time on schoolwork or activities with friends?	Pulldown List 15 ⌄
18.	c. Get schoolwork done at all or do any activities with friends?	Pulldown List 16 ⌄

3.3. During the past 4 weeks, has it been difficult to do your school work or usual activities with friends because of problems with your PHYSICAL health?

19.	a. Do certain kinds of schoolwork or activities with friends?	Pulldown List 17 ⌄
20.	b. Spend the usual amount of time on schoolwork or activities with friends?	Pulldown List 18 ⌄
21.	c. Get schoolwork done at all or do any activities with friends?	Pulldown List 19 ⌄

SECTION #4: PAIN   QSSCAT = PAIN

22.	4.1. During the past 4 weeks, how much bodily pain or discomfort have you had?	Pulldown List 20 ⌄
23.	4.2. During the past 4 weeks, how often have you had bodily pain or discomfort?	Pulldown List 21 ⌄

QSCAT=CHILD HEALTH QUESTIONNAIRE   DOMAIN: QS

CTN0028 : 2818 - Child Health Questionnaire (CHQ2)

SECTION #5: GETTING ALONG   QSSCAT = GETTING ALONG

Below is a list of items that describe children's behavior or problems they sometimes have.

5.1. During the past 4 weeks, how often did each of the following statements describe you?

		QSTEST		QSORRES
1.	a. Acted too young for your age?		Pulldown List 1	
2.	b. Argued?		Pulldown List 2	
3.	c. Had a hard time paying attention?		Pulldown List 3	
4.	d. Did not do what your teacher or parent asked you to do?		Pulldown List 4	
5.	e. Wanted to be alone?		Pulldown List 5	
6.	f. Lied or cheated?		Pulldown List 6	
7.	g. Had a hard time getting others to like you?		Pulldown List 7	
8.	h. Felt clumsy?		Pulldown List 8	
9.	i. Ran away from home?		Pulldown List 9	
10.	j. Had speech problems (e.g.,stuttering)		Pulldown List 10	
11.	k. Stole things at home		Pulldown List 11	
12.	l. Stole things outside home?		Pulldown List 12	
13.	m. Acted mean or moody if you did not get what you wanted?		Pulldown List 13	
14.	n. Got really mad when you did not get what you wanted?		Pulldown List 14	
15.	o. Found it hard to be with others?		Pulldown List 15	
16.	p. Had a hard time getting along with others?		Pulldown List 16	
17.	**5.2. Compared to other children your age, in general would you say your behavior is:**		Pulldown List 17	

SECTION #6: GENERAL WELL-BEING   QSSCAT = GENERAL WELL-BEING

6.1. During the past 4 weeks, how much time did you:

18.	a. Feel sad?		Pulldown List 18	
19.	b. Feel like crying?		Pulldown List 19	
20.	c. Feel afraid or scared?		Pulldown List 20	
21.	d. Worry about things?		Pulldown List 21	
22.	e. Feel lonely?		Pulldown List 22	
23.	f. Feel unhappy?		Pulldown List 23	
24.	g.Feel nervous?		Pulldown List 24	
25.	h. Feel bothered or upset?		Pulldown List 25	
26.	i. Feel happy?		Pulldown List 26	
27.	j. Feel cheerful?		Pulldown List 27	
28.	k. Enjoy the things you do?		Pulldown List 28	
29.	l. Have fun?		Pulldown List 29	
30.	m. Feel jittery or restless?		Pulldown List 30	
31.	n. Have trouble sleeping?		Pulldown List 31	
32.	o. Have headaches?		Pulldown List 32	
33.	p. Like yourself?		Pulldown List 33	

SECTION #7: SELF-ESTEEM   QSSCAT = SELF-ESTEEM

How do you feel about yourself, school, and others? It may be helpful if you keep in mind how other children your age might feel about these areas.

7.1. During the past 4 weeks, how good or bad have you felt about:

QSSCAT = SELF-ESTEEM   QSCAT=CHILD HEALTH QUESTIONNAIRE   DOMAIN: **QS**

		QSTEST		QSORRES
34.	a. Yourself?		Pulldown List 34	
35.	b. Your school work?		Pulldown List 35	
36.	c. Your ability to play sports?		Pulldown List 36	
37.	d. Your friendships?		Pulldown List 37	
38.	e. The things you CAN do?		Pulldown List 38	
39.	f. The way you get along with others?		Pulldown List 39	
40.	g. Your body and your looks?		Pulldown List 40	
41.	h. The way you seem to feel most of the time?		Pulldown List 41	
42.	i. The way you get along with your family?		Pulldown List 42	
43.	j. The way life seems to be for you?		Pulldown List 43	
44.	k. Your ability to be a friend to others?		Pulldown List 44	
45.	l. The way others seem to feel about you?		Pulldown List 45	
46.	m. Your ability to talk with others?		Pulldown List 46	
47.	n. Your health in general?		Pulldown List 47	

QSCAT=CHILD HEALTH QUESTIONNAIRE   **DOMAIN: QS**

	CTN0028 : 2818 - Child Health Questionnaire (CHQ3)		
	SECTION #8: YOUR HEALTH QSSCAT = YOUR HEALTH		
	The following statements are about health in general.		
	8.1. How true or false is the statement for you?		
1.	a. My health is excellent. QSTEST	Pulldown List 1 ⌄	QSORRES
2.	b. I was so sick once I thought I might die.	Pulldown List 2 ⌄	
3.	c. I do not seem to get very sick.	Pulldown List 3 ⌄	
4.	d. I seem to be less healthy than other kids I know.	Pulldown List 4 ⌄	
5.	e. I have never been very, very sick.	Pulldown List 5 ⌄	
6.	f. I always seem to get sick.	Pulldown List 6 ⌄	
7.	g. I think I will be less healthy when I get older.	Pulldown List 7 ⌄	
8.	h. I think I will be very healthy when I get older.	Pulldown List 8 ⌄	
9.	i. I never worry about my health.	Pulldown List 9 ⌄	
10.	j. I think I am healthy now.	Pulldown List 10 ⌄	
11.	k. I think I worry about my health more than other kids my age.	Pulldown List 11 ⌄	
12.	**8.2. Compared to one year ago, how would you rate your health now:**	Pulldown List 12 ⌄	
	SECTION #9: YOU AND YOUR FAMILY QSSCAT = YOU AND YOUR FAMILY		
	9.1. During the past 4 weeks, how often has your health or behavior:		
13.	a. Limited the types of activities you could do as a family?	Pulldown List 13 ⌄	
14.	b. Interrupted various everyday family activities (eating meals, watching tv)?	Pulldown List 14 ⌄	
15.	c. Limited your ability as as family to "pick up and go" on a moment's notice?	Pulldown List 15 ⌄	
16.	d. Caused tension or conflict in your home?	Pulldown List 16 ⌄	
17.	e. Been a source of disagreements or arguments in your family?	Pulldown List 17 ⌄	
18.	f. Caused your family to cancel or change plans at the last minute?	Pulldown List 18 ⌄	
19.	**9.2. Sometimes families may have difficulty getting along with one another. They do not always agree and they may get angry. In general, how would you rate your family's ability to get along with one another?**	Pulldown List 19 ⌄	
	SECTION # 10: FACTS ABOUT YOU QSSCAT = FACTS ABOUT YOU		
20.	**10.1. Are you:**	[1] ○ 1 Male [2] ○ 2 Female [98] ○ NA	
21.	**10.2. What is your date of birth?**	[99] ○ Req ⌄ / Req ⌄ / Req ⌄ (1985-2008) [98] ○ NA	
22.	**10.3. What is the highest grade of school you have completed?**	Pulldown List 20 ⌄ If ungraded, how many years attended? xx	
23.	**10.4. Have you ever seen someone at school, clinic or doctor's office for any of the following:** a. Injuries due to accidents?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA	
24.	b. Bed wetting?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA	
25.	c. Chest pain?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA	
26.	d. Diarrhea or constipation?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA	
27.	e. Not having a lot of energy to do things for a long time?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA	
28.	f. Headaches?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA	
29.	g. Not feeling like eating very much for a long time?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA	
30.	h. Bad dreams, trouble falling asleep or staying asleep?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA	
31.	i. Stomach aches?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA	
32.	10.5. What is today's date?	[99] ○ Req/Unk ⌄ / Req/Unk ⌄ / Req ⌄ (1950-2008) [98] ○ NA	

QSCAT=TEEN HEALTH SURVEY

DOMAIN: **QS**

	CTN0028 : 2820 - Teen Health Survey (THS1)	
1.	Assessment Date	NReq ▾ / NReq ▾ / NReq ▾ (2005-2008) (mm/dd/yyyy)
2.	Visit Number	[99] ○ xxx [98] ○ NA
3.	1. Are you male or female?	Select One: [1] ○ 1 Male [2] ○ 2 Female [98] ○ NA
4.	2. How old are you?	Select One: Pulldown List 1 ▾
5.	3. What grade are you in?	Select One: Pulldown List 2 ▾
6.	4. What is your ethnic background?	Select all that apply: [1] ☐ 1 White [2] ☐ 2 African-American [3] ☐ 3 Hispanic-American [4] ☐ 4 Native American [5] ☐ 5 Asian or Pacific Islander [6] ☐ Other (please list) A20 [98] ☐ NA
7.	5. I live with my:	Select One: Pulldown List 3 ▾ If Other, please list: A24
8.	6. What is the highest level of education of any of the adults who live in your home?	Select One: Pulldown List 4 ▾
9.	7. What do you think your household income is per year?	Select One: Pulldown List 5 ▾

QSDTC

VISITNUM/VISIT

QSTEST

QSORRES

QSCAT=TEEN HEALTH SURVEY **DOMAIN: QS**

	CTN0028 : 2820 - Teen Health Survey (THS2)		
1.	1. If you love and trust someone, you don't have to worry about getting HIV from them.	Select one: Pulldown List 1	
2.	2. You can tell whether someone has HIV by the way they look.	Select one: Pulldown List 2	
3.	3. Only people who are homosexual or who use drugs really have to worry about getting HIV.	Select one: Pulldown List 3	
4.	4. If you know a person very well, you don't have to use condoms to protect against getting HIV from them.	Select one: Pulldown List 4	
5.	5. You don't have to use a condom for HIV protection if you are in a relationship with just one person, even if that person had unprotected sex with other people before.	Select one: Pulldown List 5	
6.	6. If your boyfriend or girlfriend is not a drug user, you don't need to worry about getting HIV from them.	Select one: Pulldown List 6	
7.	7. You can tell by the way a person acts if you can get HIV or AIDS from them.	Select one: Pulldown List 7	
8.	8. It's more important to use condoms in one night stands and flings than in real relationships.	Select one: Pulldown List 8	
9.	9. Using latex condoms (rubbers) during sex can protect you from getting HIV.	Select one: Pulldown List 9	
10.	10. Vaseline or baby oil should never be used with condoms.	Select one: Pulldown List 10	
11.	11. You can safely store condoms in your wallet for at least two months.	Select one: Pulldown List 11	
12.	12. Not having sexual intercourse (sex in which a penis is put into a vagina or rectum) can help protect you from getting HIV.	Select one: Pulldown List 12	
13.	13. Women with HIV can give it to their babies through breast milk.	Select one: Pulldown List 13	
14.	14. You can get HIV by sharing a needle with someone who has it.	Select one: Pulldown List 14	
15.	15. "Pulling out" before the male ejaculates prevents the spread of HIV.	Select one: Pulldown List 15	
16.	16. There is nothing a mother who has HIV or AIDS can do to protect her baby from getting it.	Select one: Pulldown List 16	
17.	17. If you have sex and have an HIV test the next day, it can definitely tell you if you got HIV.	Select one: Pulldown List 17	
18.	18. Some people have gotten HIV by sharing forks, knives, or glasses with a person who has AIDS.	Select one: Pulldown List 18	
19.	19. You are less likely to get HIV from oral sex than from anal sex (oral means putting your mouth on a penis or vagina, anal sex means putting the penis in the anus or rectum).	Select one: Pulldown List 19	
20.	20. You are just as likely to get HIV from kissing an infected person as from having sex with them.	Select one: Pulldown List 20	
21.	21. There is a medicine that completely cures AIDS.	Select one: Pulldown List 21	
22.	22. The most important time to use condoms with someone is when you have sex with them for the first time.	Select one: Pulldown List 22	
23.	23. Making sure you don't have a lot of sex partners will protect you from HIV.	Select one: Pulldown List 23	

QSTEST **QSORRES**

QSCAT=TEEN HEALTH SURVEY   **DOMAIN: QS**

CTN0028 : 2820 - Teen Health Survey (THS3)

Please tell us your thoughts about *not having sexual intercourse at all* until you are older (by sexual intercourse, we mean putting the penis in the vagina or rectum):

QSTEST   **QSORRES**

1.	1. For me, not having sex until I am older would be:	Select one: Pulldown List 1	
2.	2. Friends that I respect think I should not have sex until I'm older:	Select one: Pulldown List 2	
3.	3. My boyfriend or girlfriend thinks we should not have sex until we're older:	Select one: Pulldown List 3	
4.	4. I'm planning not to have sex until I'm older.	Select one: Pulldown List 4	

These questions are about talking to a boyfriend or a girlfriend about whether or not you should have sex.

5.	5. Talking to my boyfriend or girlfriend about whether or not we should have sex would be:	Select one: Pulldown List 5	
6.	6. Friends my age that I respect think I should talk to my boyfriend or girlfriend about whether or not we should have sex:	Select one: Pulldown List 6	
7.	7. My boyfriend or girlfriend thinks we should talk about whether or not to have sex:	Select one: Pulldown List 7	
8.	8. I'm planning to talk to my boyfriend or girlfriend about whether or not we should have sex:	Select one: Pulldown List 8	

These questions are about buying condoms or getting them for free during the next two months:

9.	9. For me, buying condoms or getting them for free during the next two months would be:	Select one: Pulldown List 9	
10.	10. Friends that I respect think I should buy condoms or get them for free, during the next two months.	Select one: Pulldown List 10	
11.	11. My boyfriend or girlfriend thinks I should buy condoms or get them for free, during the next two months.	Select one: Pulldown List 11	
12.	12. During the next two months, I'm planning to buy condoms or get them for free.	Select one: Pulldown List 12	

Please tell us what you think about carrying condoms with you (for example, in your backpack or purse) during the next two months:

13.	13. During the next two months, carrying condoms with me would be:	Select one: Pulldown List 13	
14.	14. Friends that I respect think I should carry condoms with me during the next two months.	Select one: Pulldown List 14	
15.	15. My boyfriend or girlfriend thinks I should carry condoms with me during the next two months.	Select one: Pulldown List 15	
16.	16. During the next two months, I'm planning to carry condoms with me.	Select one: Pulldown List 16	

Tell us how you feel about using condoms every time you have sex during the next two months.
If you do not think you will have sex during the next two months, answer all of the questions below anyway. When you answer, tell us what it would be like to use condoms if you *did* have sex.

17.	17. If I have sex during the next two months, using condoms every time would be:	Select one: Pulldown List 17	
18.	18. Friends that I respect think I should use condoms every time, if I have sex, during the next two months.	Select one: Pulldown List 18	
19.	19. My boyfriend or girlfriend thinks I should use condoms every time, if I have sex, during the next two months.	Select one: Pulldown List 19	
20.	20. If I have sex during the next two months, I'm planning to use condoms every time.	Select one: Pulldown List 20	

Please tell us about telling your boyfriend or girlfriend to use condoms with you, if you have sex during the next two months.
Even if you do not have a boyfriend or a girlfriend right now, or if you do not think you are going to have sex during the next two months, tell us what you *think* it would be like to tell a boyfriend or girlfriend to use condoms with you.

21.	21. If we have sex during the next two months, telling my boyfriend or girlfriend we have to use condoms would be:	Select one: Pulldown List 21	
22.	22. Friends that I respect think I should tell my boyfriend or girlfriend we have to use condoms, if we have sex, during the next two months.	Select one: Pulldown List 22	
23.	23. My boyfriend/girlfriend thinks that I should tell them we have to use condoms, if we have sex during the next two months.	Select one: Pulldown List 23	
24.	24. If I have sex during the next two months, I'm planning to tell my boyfriend or girlfriend we have to use condoms.	Select one: Pulldown List 24	

Please tell us what you think about the risk of getting HIV or AIDS.

25.	1. What do you think are your friends' chances of getting HIV/AIDS?	Select one: Pulldown List 25	
26.	2. What do you think are your own chances of getting HIV/AIDS?	Select one: Pulldown List 26	
27.	3. How afraid are yo of getting HIV/AIDS?	Select one: Pulldown List 27	

Please tell us what you think about abstaining from sex (not having sex at all, until you are older):

28.	1. I think it would be good if I didn't have sex until I was older.	Select one: Pulldown List 28	
29.	2. People who don't have sex until they're older are very responsible.	Select one: Pulldown List 29	
30.	3. People who don't have sex until they're older are usually unpopular people.	Select one: Pulldown List 30	
31.	4. You can still be very affectionate with a boyfriend or girlfriend, even if you don't have sex.	Select one: Pulldown List 31	

QSCAT=TEEN HEALTH SURVEY   DOMAIN: QS

		QSTEST			QSORRES
32.	5. I have friends who don't plan on having sex until they're older.	Select one:	Pulldown List 32		
	Please tell us what you think about using condoms. Please try to answer every question, even if you have never had sex or used a condom. Just do the best you can.				
33.	6. I like having sex with condoms.	Select one:	Pulldown List 33		
34.	7. People who use condoms are very responsible.	Select one:	Pulldown List 34		
35.	8. Condoms take all the fun out of sex.	Select one:	Pulldown List 35		
36.	9. If you want to use a condom, your boyfriend or girlfriend might think you don't trust them.	Select one:	Pulldown List 36		
37.	10. Most of my friends use condoms if they have sex.	Select one:	Pulldown List 37		

QSCAT=TEEN HEALTH SURVEY   DOMAIN: **QS**

QSTEST

QSORRES

	CTN0028 : 2820 - Teen Health Survey (THS4)		
1.	1. How hard or easy would it be for you to make sure you do not have sexual intercourse until you're older?	Select one: Pulldown List 1 ▾	
2.	2. How hard or easy would it be for you to tell your boyfriend or girlfriend you are not going to have sex with them? (If you don't have a boyfriend or girlfriend, please answer as if you had one).	Select one: Pulldown List 2 ▾	
3.	3. How hard or easy would it be for you to get condoms (buy them or get them free) at a place close to your home or school?	Select one: Pulldown List 3 ▾	
4.	4. How hard or easy would it be for you to carry condoms with you so they would be handy if you had sex?	Select one: Pulldown List 4 ▾	
5.	5. If you have sex, how hard or easy would it be for you to make sure you and your partner use a condom every time?	Select one: Pulldown List 5 ▾	
6.	6. If you have sex, how hard or easy would it be for you to make sure you and your partner use a condom every time, if you were under the influence of alcohol or drugs?	Select one: Pulldown List 6 ▾	
7.	7. How hard or easy would it be for you to talk about using condoms with your boyfriend or girlfriend? (If you don't have a boyfriend or girlfriend, please answer as if you had one).	Select one: Pulldown List 7 ▾	
8.	1. Have you *ever* had sexual intercourse?	Select one: [1] ○ 1 Yes, I have had [0] ○ 0 No, I have never had sexual intercourse [98] ○ NA	
9.	2. Have you had sexual intercourse *during the past two months*?	Select one: [1] ○ 1 Yes, I have had sexual intercourse during the past two months [0] ○ 0 No, I have not had sexual intercourse during the past two months [98] ○ NA	
10.	3. *During the past 2 months*, how often did you say no to having sex when somebody asked you to have sex with them?	Select one: Pulldown List 8 ▾	
11.	4. During the past 2 months, how often did you stay out of situations where you might have sexual intercourse (like being home alone with your boyfriend/girlfriend) to make sure you didn't have sex?	Select one: Pulldown List 9 ▾	
12.	5. During the past 2 months, how often did you buy condoms (or get them for free)?	Select one: Pulldown List 10 ▾	
13.	6. During the past 2 months, how often did you carry condoms and keep them handy?	Select one: Pulldown List 11 ▾	
14.	7. During the past 2 months, how often did you tell your boyfriend or girlfriend to use condoms with you?	Select one: Pulldown List 12 ▾	
15.	8. *During the past two months*, how often have you and your partner used condoms when you had sexual intercourse?	Select one: Pulldown List 13 ▾	
16.	9. *During the past two months*, how often have you used drugs or alcohol when you had sexual intercourse?	Select one: Pulldown List 14 ▾	
17.	10. *During the past two months*, how many people did you have sexual intercourse with?	Please write the number of people here: xxx	
18.	11. Which of these is true for you?	Select one: [1] ○ 1 If I had sexual intercourse, I would have it only with men. [2] ○ 2 If I had sexual intercourse, I would have it only with women. [3] ○ 3 If I had sexual intercourse, I would have it with either men or women. [98] ○ NA	
19.	12. Have you ever had an HIV blood test to find out whether you have been exposed to the virus that causes AIDS?	Select one: [1] ○ 1 Yes [0] ○ 0 No [98] ○ NA	
20.	13. Are you in a relationship right now?	Select one: [1] ○ Yes, I am in a relationship [0] ○ No, I am not in a relationship [98] ○ NA	
21.	14. How long have you been in this relationship?	Write the number of MONTHS here: xxx Or select one: [1] ○ 1 Does not apply; I am not in a relationship [98] ○ NA	
22.	15. Have you ever had a sexually transmitted disease like chlamydia, herpes, or warts?	Select one: [1] ○ 1 Yes [0] ○ 0 No [98] ○ NA	
23.	16. Have you ever been pregnant (if you are a girl) or gotten somebody else pregnant (if you are a boy)?	Select one: [1] ○ 1 Yes [0] ○ 0 No [98] ○ NA	
24.	17. If you have ever had sex, how old were you the *first* time you had sex?	Please write how old you were here: xx Or select one: [1] ○ 1 Does not apply; I have never had sex [98] ○ NA	
25.	18. When you have sexual intercourse, how often do you use a condom?	Select one: Pulldown List 15 ▾	

QSCAT=URICA **DOMAIN: QS**

	CTN0028 : 2822 - URICA (URC p1)	
1.	Assessment Date	NReq / NReq / NReq (2005-2008) (mm/dd/yyyy)
2.	Visit Number	[99] ○ xxx [98] ○ NA
3.	1. As far as I'm concerned, I don't have any problems that need changing.	Pulldown List 1
4.	2. I think I might be ready for some self-improvement.	Pulldown List 1
5.	3. I am doing something about the problems that have been bothering me.	Pulldown List 1
6.	4. It might be worthwhile to work on my problem.	Pulldown List 1
7.	5. I'm not the problem one. It doesn't make much sense for me to be here.	Pulldown List 1
8.	6. It worries me that I might slip back on a problem I have already changed, so I am here to seek help.	Pulldown List 1
9.	7. I am finally doing some work on my problem.	Pulldown List 1
10.	8. I've been thinking that I might want to change something about myself.	Pulldown List 1
11.	9. I have been successful in working on my problem, but I'm not sure I can keep up the effort on my own.	Pulldown List 1
12.	10. At times my problem is difficult, but I'm working on it.	Pulldown List 1
13.	11. Being here is pretty much a waste of time for me because the problem doesn't have much to do with me.	Pulldown List 1
14.	12. I'm hoping this place will help me to better understand myself.	Pulldown List 1
15.	13. I guess I have faults, but there's nothing I really need to change.	Pulldown List 1
16.	14. I am really working hard to change.	Pulldown List 1
17.	15. I have a problem, and I really think I should work on it.	Pulldown List 1
18.	16. I'm not following through with what I had already changed as well as I had hoped, and Im here to prevent a relapse of the problem.	Pulldown List 1
19.	17. Even though I'm not always successful in changing, I am at least working on my problem.	Pulldown List 1
20.	18. I thought once I had resolved the problem, I would be free of it, but sometimes I still find myself struggling with it.	Pulldown List 1

QSDTC

VISITNUM/VISIT

QSTEST   QSORRES

QSCAT=URICA

DOMAIN: **QS**

	CTN0028 : 2822 - URICA Contd (URC p2)		
	URICA Contd		
1.	19. I wish I had more ideas on how to solve my problem.	Pulldown List 1	
2.	20. I have started working on my problem, but I would like help.	Pulldown List 1	
3.	21. Maybe this place will be able to help me.	Pulldown List 1	
4.	22. I may need a boost right now to help me maintain the changes I've already made.	Pulldown List 1	
5.	23. I may be part of the problem, but I don't really think I am.	Pulldown List 1	
6.	24. I hope that someone here will have some good advice for me.	Pulldown List 1	
7.	25. Anyone can talk about changing; I'm actually doing something about it.	Pulldown List 1	
8.	26. All this talk about psychology is boring. Why can't people just forget about their problems?	Pulldown List 1	
9.	27. I'm here to prevent myself from having a relapse of my problem.	Pulldown List 1	
10.	28. It is frustrating, but I feel I might be having a recurrence of a problem I thought I had resolved.	Pulldown List 1	
11.	29. I have worries, but so does the next guy. Why spend time thinking about them?	Pulldown List 1	
12.	30. I am actively working on my problem.	Pulldown List 1	
13.	31. I would rather cope with my faults than try to change them.	Pulldown List 1	
14.	32. After all I had done to try and change my problem, every now and again it comes back to haunt me.	Pulldown List 1	

QSTEST

QSORRES

QSCAT=ADOLESCENT RELAPSE COPING QUESTIONNAIRE   **DOMAIN: QS**

	CTN0028 : 2828-Adolescent Relapse Coping Questionnaire (ARC)	
1.	Assessment Date **QSDTC**	Req ▾ / Req ▾ / Req ▾ (2005-2008) (mm/dd/yyyy)
2.	Visit Number **VISITNUM/VISIT**	[99] ○ xxx [98] ○ NA

A. Imagine if you found yourself in this situation:
You arrive at a friend's house in the evening. There are a few other people, everyone is sitting around talking, drinking and using drugs. When you sit down, you are offered drugs and something to drink.   **QSTEST**   **QSORRES**

3.	1. Have you ever been in a situation like this?	Pulldown List 1 ▾
4.	2. How difficult would this situation be for you? How hard to cope with?	Pulldown List 2 ▾
5.	3. How much would you want to drink or use in this situation? How much of an urge would you have?	Pulldown List 3 ▾
6.	4. How much of a risk for relapse (i.e., drinking and/or using) is this situation?	Pulldown List 4 ▾
7.	5. How important is it that you don't drink or use in this situation?	Pulldown List 5 ▾
8.	6. How likely do you think it is that you would be able to keep from drinking and/or using (i.e., not drink or use) in this situation?	Pulldown List 6 ▾

Rember this Situation:
You arrive at a friends house in the evening. There are a few other people, everyone is sitting around talking, drinking and using drugs. When you sit down, you are offered drugs and something to drink.
B. Please indicate below numbered from 1 to 7 what you would think or do in this situation to avoid using drugs and/or alchohol:

9.	1) Use the support of a higher power (for example, pray, meditate).	Pulldown List 7 ▾
10.	2) Do something instead of using or drinking (watch TV, socialize).	Pulldown List 8 ▾
11.	3) Make a promise to yourself that things will be different next time.	Pulldown List 9 ▾
12.	4) Just concentrate on what you have to do next -- the next step (in the situation or afterwards).	Pulldown List 10 ▾
13.	5) Think of a better time or place than the one you are in -- imagine things that make you feel better.	Pulldown List 11 ▾
14.	6. Stand your ground and fight for what you want (for example, do what you think is right regardless of other's opinions).	Pulldown List 12 ▾
15.	7) Wish you were a stronger person.	Pulldown List 13 ▾
16.	8) Change something so things will turn out all right (for example, get out of the situation).	Pulldown List 14 ▾
17.	9) Think to yourself you don't want to blow your sobriety, or go back to drinking and/or using drugs.	Pulldown List 15 ▾
18.	10) Come up with a couple of different ways to handle the situation (for example, think about ways to avoid negative consequences).	Pulldown List 16 ▾
19.	11) Change something about yourself so you can deal with the situation better (for example, decide to be more patient, have more willpower, etc.)	Pulldown List 17 ▾
20.	12) Let your feelings out somehow.	Pulldown List 18 ▾
21.	13) Realize you brought the situation on yourself; blame yourself.	Pulldown List 19 ▾
22.	14) Leave or avoid the situation.	Pulldown List 20 ▾
23.	15) Discover what is important in life (think that you'll learn something important about yourself, change your priorities, etc. as a result of your experience).	Pulldown List 21 ▾
24.	16) Use self-control or will power.	Pulldown List 22 ▾
25.	17) Try to forget the whole thing.	Pulldown List 23 ▾
26.	18) Criticize or lecture yourself.	Pulldown List 24 ▾
27.	19) Think you would feel guilty if you use or drink.	Pulldown List 25 ▾
28.	20) Keep others from knowing how bad things are.	Pulldown List 26 ▾
29.	21) Think that drinking or using is bad, you don't want to be part of it.	Pulldown List 27 ▾
30.	22) Talk to someone to find out more about the situation (for example, to find out how you could avoid the situation and its consequences if it comes up again).	Pulldown List 28 ▾
31.	23) Contact a support for staying clean (for example, call a sponsor or sober friend, go to NA/AA meeting).	Pulldown List 29 ▾
32.	24) Do something which you think won't work but at least you're doing something (for example, try to refuse alcohol or drugs even if you think you'll give in eventually).	Pulldown List 30 ▾
33.	25) Make a plan of action and follow it (for example, plan in advance how you would act in this type of situation).	Pulldown List 31 ▾
34.	26) Try to look on the bright side of things, look for something good that could come out of the situation.	Pulldown List 32 ▾
35.	27) Think others who matter to you (friends, family) will be upset.	Pulldown List 33 ▾
36.	28) Wish that you could change what had happened (for example, feel bad that you couldn't avoid the situation).	Pulldown List 34 ▾

EGCAT=ECG RESULTS   DOMAIN: EG

CTN0028 : 2843 - ECG (ECG)		
1.	Assessment Date *(EGDTC)*	Req ▾ / Req ▾ / Req ▾ (2005-2008) (mm/dd/yyyy)
2.	Visit Number *(VISITNUM/VISIT)*	[99] ○ xxx [98] ○ NA
A. ECG Overall Results		
3.	ECG overall results *(EGTEST)*	[0] ○ 0 Normal [1] ○ 1 Abnormal [98] ○ NA *(EGORRES)*
B. Specific ECG Abnormalities		
4.	2. Increased QRS Voltage	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
5.	3. QTc Prolongation	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
6.	4. Left Atrial Hypertrophy	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
7.	5. Right Atrial Hypertrophy	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
8.	6. Left Ventricular Hypertrophy	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
9.	7. Right Ventricular Hypertrophy	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
10.	8. Acute Infarction	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
11.	9.Subacute Infarction	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
12.	10. Old Infarction	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
13.	11. Myocardial Ischemia	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
14.	12. Digitalis Effect	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
15.	13. Symmetrical T-wave inversions	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
16.	14. Poor R-Wave Progression	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
17.	15. Other Nonspecific ST/T	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
18.	16. Sinus Tachycardia	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
19.	17.Sinus Bradycardia	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
20.	18. Superventricular Premature Beat	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
21.	19.Ventricular Premature Beat	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
22.	20. Supraventricular Tachycardia	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
23.	21. Ventricular Tachycardia	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
24.	22. Atrial Fibrillation	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
25.	23. Atrial Flutter	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
26.	24. Other Rhythm Abnormalities	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
27.	25. Implanted Pacemaker	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
28.	26. 1st Degree A-V Block	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
29.	27. 2nd Degree A-V Block	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
30.	28. 3rd Degree A-V Block	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
31.	29. LBB Block	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
32.	30. RBB Block	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
33.	31. Pre-excitation Syndrome	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
34.	32. Other Intraventricular Condition Block	[1] ○ 1 Abnormal [2] ○ 2 Abnormal Excludes [98] ○ NA
35.*	33. Other Abnormality	[99] ○ specify: A200 [98] ○ NA
36.	34. Ventricular rate (bpm): *(EGORRESU)*	[99] ○ xxx [98] ○ NA
37.	35. QRS (ms):	[99] ○ xxx [98] ○ NA
38.	36. PR (ms):	[99] ○ xxx [98] ○ NA
39.	37. QTc (ms):	[99] ○ xxx [98] ○ NA
* Item is not required		

QNAM=OTHERAB
QLABEL=OTHER ABNORMALITY
IDVAR=EGSEQ

DOMAIN: IE SC

CTN0028 : 2821 - Study Eligibility (SEL)

1.	Assessment Date	Req ▾ / Req ▾ / Req ▾ (2005-2008) (mm/dd/yyyy)
2.	Visit Number	[99] ○ xxx [98] ○ NA

IEDTC (Assessment Date)

VISITNUM/VISIT (Visit Number)

Inclusion Criteria

IECAT=INCLUSION CRITERIA   **IETEST**   **IEORRES**

3.	1. Adolescents aged 13 through 18	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed
4.	2. Meet DSM-IV diagnostic criteria for ADHD as determined by the KSADS-E	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed
5.	3. Meet DSM-IV criteria for at least one non-nicotine substance use disorder (abuse or dependence) except current opiate dependence or current methamphetamine abuse or dependence AND have used a non-nicotine substance (except methamphetamine) within 28 days prior to signing consent	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed
6.	4. Is willing to participate in concurrent drug treatment (CBT) during the 16 week medication trial	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed
7.	5. Are likely to be in the area for 6 months and able to attend weekly outpatient treatment for the 4 month duration of the active study	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed
8.	6. Are able to understand and provide written informed consent (or assent if a non-emancipated minor)	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed
9.	7. Parent or guardian able to understand and willing to provide written informed consent (if participant is a non-emancipated minor)	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed
10.	8. Has a DSM-IV ADHD Symptom checklist score >=22 derived from the adolescent-completed checklist and, if the adolescent is a non-emancipated minor, a score >=22 derived from a joint adolescent and parent/guardian checklist	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed
11.	9. If female and of child bearing potential, agrees to use one of the following methods of birth control: -Complete abstinence from sexual intercourse -Oral contraceptive -Patch -Barrier (diaphragm or condom) -Intrauterine contraceptive system -Levonorgestrel implant -Medroxyprogesterone acetate contraceptive injection -Hormonal vaginal contraceptive ring	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed

Exclusion Criteria

IECAT=EXCLUSION CRITERIA

12.	10. Serious medical illness or other clinical issues that, in the judgement of the medical clinician (MC) or site physician (SP), would make study participation unsafe	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed
13.	11. History of tic disorder	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed
14.	12. Pregnancy	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed
15.	13. Breastfeeding	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed
16.	14. Meet DSM-IV criteria for current or life-time psychotic disorder as determined by K-SADS-E and confirmed by the SP	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed
17.	15. Meet DSM-IV criteria for current or life-time bipolar disorder as determined by K-SADS-E and confirmed by the SP	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed
18.	16. Requires or is currently taking other concurrent psychotropic medication.(the SP should complete this question based on his/her review of relevant assessments - e.g., K-SADS, medical history, etc.)	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed
19.	17. Taking any medications listed in protocol section 8.10 and/or those which, in the judgement of the MC or SP, may produce interactions with OROS-MPH that are sufficiently dangerous so as to exclude the patient from participating in the study.	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed
20.	18. Meet DSM-IV criteria for current opiate dependence as determined by CIDI	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed
21.	19. Meet DSM-IV criteria for current methamphetamine abuse or dependence as determined by the CIDI or reports past 28 day use of methamphetamine, or has a positive urine drug screen for methamphetamine at baseline assessment	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed
22.	20. A significant suicidal risk, as determined by clinical assessment	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed
23.	21. Active participation in substance abuse treatment or mental health treatment (including outpatient, day-treatment, residential, or inpatient) within 28 days prior to signing consent	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed
24.	22. In the judgement of the MC or SP, requires additional or more intensive (e.g., inpatient, residential) treatment setting as assessed at screening/baseline	[1] ○ 1 Yes [0] ○ 0 No [-5] ○ -5 Not Assessed
25.	23. Is the individual: Eligible for the study?	[1] ○ 1 Yes [0] ○ 0 No

SCTEST   **SCORRES**

SCCAT=ELIGIBLE FOR STUDY

DOMAIN: **DM,DS,SC**

CTN0028 : 2823 - Randomization (RAN)		
1. Assessment Date DM/DS/SC/DTC	Req ▾ / Req ▾ / Req ▾ (2005-2008) (mm/dd/yyyy)	
2. Visit Number VISITNUM/VISIT	[99] ○ xxx [98] ○ NA SCCAT=RANDOMIZATION	
SECTION 1 *Must be completed prior to randomizing the study candidate*		
3. 1. Has it been determined that the individual is eligible for the study, as defined by the inclusion/exclusion criteria?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA SCTEST SCORRES	
SECTION 2		
Complete Randomization Procedure		
4. 2. Medication Kit Number assigned to participant?	[99] ○ xxxxxxxxxx [98] ○ NA	
5. 3. Date of Randomization?	[99] ○ Req ▾ / Req ▾ / Req ▾ (2005-2009) (mm/dd/yyyy) [98] ○ NA DM.RFSTDTC / DS.DSSTDTC	
6. 4. If Participant was eligible, but not randomized, please mark reason: DSTERM	[1] ○ 1 No longer interested in participating in the study [2] ○ 2 Left prior to randomization and failed to return DSDECOD [3] ○ 3 Other, Specify: [A50] [98] ○ NA	

DSCAT=DISPOSITION EVENT

Never Entered

QNAM=DSKITNO
QLABEL=MEDICATION KIT NUMBER
IDVAR=DSSEQ

QSCAT=RESERCH VISIT COMPLIANCE

DOMAIN: **QS**

	CTN0028 : 2827 - Research Visit Compliance (RVC)		
1.	Assessment Date		Req ⌄ / Req ⌄ / Req ⌄ (2005-2008) (mm/dd/yyyy)
2.	Visit Number		[99] ○ xxx [98] ○ NA
3.	1. Study Week for which compliance is being assessed		[99] ○ xx [98] ○ NA
4.	2. How many visits were scheduled during the study week?		[99] ○ xx [98] ○ NA
5.	3. How many visits were attended during the study week?		[99] ○ xx [98] ○ NA
6.	4. How many scheduled visits did the participant miss?		[99] ○ xx [98] ○ NA
7.	5. How many visits did study staff cancel?		[99] ○ xx [98] ○ NA
8.	6. Did the participant complete the assessments and procedures scheduled for the visit?		[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA
9.*	7. Comments		A200
*	Item is not required		

QSDTC

VISITNUM/VISIT

QSTEST

QSORRES

CO.COVAL

IDVAR=QSSEQ

QSCAT=CLINICAL TREATMENT SESSION SUMMARY (CTS)   **DOMAIN: QS**

	CTN0028 : 2839-CBT Clinician Treatment Session Summary - Individual (CTS)	
1.	Assessment Date **QSDTC**	Req ▾ / Req ▾ / Req ▾ (2005-2008) (mm/dd/yyyy)
2.	Visit Number **VISITNUM/VISIT**	[99] ○ xxx [98] ○ NA
	I. Session Information **QSTEST** **QSORRES**	
3.	1. CBT Module:	Pulldown List 1 ▾
4.	1.a If Session Topic is "16-Combination Skills" then record the topic codes for all skills that were used during this session. There should be no more than two chosen in combination:	[99] ○ Topic Number: xx and Topic Number: xx [98] ○ NA
	A. Activity Since Last Session	
5.	2. How long has it been since your last session?	[99] ○ xx (days) [98] ○ NA
6.	3. How many appointments were scheduled since the last session?	[99] ○ xx [98] ○ NA
7.	4. How many appointments did the client no show to?	[99] ○ xx [98] ○ NA
8.	5. How many appointments did the client cancel?	[99] ○ xx [98] ○ NA
9.	6. How many appointments did you cancel?	[99] ○ xx [98] ○ NA
	B. Information About Today's Session	
10.	7. How long was today's session? (in minutes)	[99] ○ xxx [98] ○ NA
11.	8. Did you record and label the audiotape with your ID, the participant's ID, study week, the session topic, and date?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA
12.	9. Are there problems the investigators or coordinator should know about?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA
	II. Treatment Adherence Checklist	
13.	11. To what extent did you review the participant's at-home practice and, as necessary, address any difficulties in carrying out the assignment; provide a reminder of the rationale and importance of extra-session practice; and give an opportunity to complete during session if it was not done?	Pulldown List 2 ▾
14.	12. To what extent did you assess the participant's use of substances since the last session including exploring high-risk situations s/he encountered?	Pulldown List 3 ▾
15.	13. To what extent did you elicit participation in selecting one specific session topic and provide a rationale to the participant for why these skills are being covered during this session?	Pulldown List 4 ▾
16.	14. To what extend did you teach and model specific skills (e.g. explaining new skills step-by-step using relevant examples from the participant's life)?	Pulldown List 5 ▾
17.	15. To what extent did you involve the participant in the in-session practice in order to rehearse the new skills learned (e.g. behavior rehearsal role plays or other relevant practice exercises as suggested in the intervention manual)?	Pulldown List 6 ▾
18.	16. To what extent did you keep the session focused on prescribed activities (e.g. by redirecting dialogue when it strayed off task and by organizing the session so defined tasks were covered) and balance this with maintaining an empathic listening style?	Pulldown List 7 ▾
19.	17. To what extent did you develop one or more specific and realistic at-home practice assignments for the participant to engage in between sessions and explain how to do this to the participant?	Pulldown List 8 ▾
20.	18. Comments. Note: If Session Topic was "Other" session (# 17), please briefly indicate rationale for diverging from skills:	[98] ○ NA [1] ○ A200

EXCAT=TREATMENT COMPLIANCE – PARTICIPANT REPORT   **DOMAIN: EX/CO**

#	Assessment Date	Visit Number	Sequence Number	Study Week	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Dat 7	
1												

CTN0028 : 2826 - Treatment Compliance - Medication - Participant Report (TCM) - Repeating Form

1.	Assessment Date	**EXDTC**	Req ▾ / Req ▾ / Req ▾ (2005-2008) (mm/dd/yyyy)
2.	Visit Number	**VISITNUM/VISIT**	[99] ○ xxx [98] ○ NA
3.	Sequence Number		[99] ○ xx [98] ○ NA

Medication - Participant Report

4.	1. Study Week being assessed:	**EXSPID** **EXDOSRGM** **EXDOSE**	[99] ○ xx [98] ○ NA
5.	Day 1		[99] ○ A. Date (mm/dd/yyyy) B. #pills presc C. #pills taken D. Comments [98] ○ NA
			Req ▾ / Req ▾ / Req ▾ (2005-2008)	xx		xx	A200 **CO.COVAL IDVAR=EXSEQ**
6.	Day 2		[99] ○ Req ▾ / Req ▾ / Req ▾ (2005-2008)	xx	xx	A200 [98] ○ NA
7.	Day 3		[99] ○ Req ▾ / Req ▾ / Req ▾ (2005-2008)	xx	xx	A200 [98] ○ NA
8.	Day 4		[99] ○ Req ▾ / Req ▾ / Req ▾ (2005-2008)	xx	xx	A200 [98] ○ NA
9.	Day 5		[99] ○ Req ▾ / Req ▾ / Req ▾ (2005-2008)	xx	xx	A200 [98] ○ NA
10.	Day 6		[99] ○ Req ▾ / Req ▾ / Req ▾ (2005-2008)	xx	xx	A200 [98] ○ NA
11.	Day 7		[99] ○ Req ▾ / Req ▾ / Req ▾ (2005-2008)	xx	xx	A200 [98] ○ NA

EXSTDTC

SEQUENCE NUMBER NOT USED. GENERATED SEQUENCE
NUMBER FROM DATA INSTEAD (SEE EXSEQ)

QSCAT=ACTIVE STUDY (TLA)   DOMAIN: **QS**

CTN0028 : 2834 - TLFB - Active Study (TLA) - Repeating Form

#	Assessment Date	Visit Number	Sequence Number	Primary Drug	Drug Informati
1					

1.	Assessment Date	NReq / NReq / NReq (2005-2008) (mm/dd/yyyy)	
2.	Visit Number	[99] ○ xxx [98] ○ NA	
3.	Sequence Number	[99] ○ xx [98] ○ NA	
4.	1. Primary Drug	Pulldown List 1 ⌄ Specify other │ A50	

QSDTC
VISITNUM/VISIT

SEQUENCE NUMBER NOT USED. GENERATED SEQUENCE NUMBER FROM DATA INSTEAD (SEE EXSEQ)

QSTEST   │   QSORRES

	Day	Date	Alcohol standard drinks	Marijuana joints	Cigarettes cpd	Other Tobac	OTC Meds	Cocaine	Cocaine Route	Amphetamine	Am Rou
5.											

Drug Information Entry

QSTEST   QSORRES

5.a	Day	Pulldown List 2 ⌄
5.b	2. Date	[99] ○ Req / Req / Req (2005-2008) [98] ○ NA
5.c	3. Alcohol	[99] ○ # Stnd Drinks xxx [98] ○ NA
5.d	4. Marijuana	[99] ○ # jnts xxx [98] ○ NA
5.e	5. Cigarettes	[99] ○ # cpd xxx [98] ○ NA
5.f	6. Other Tobac	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.g	7. OTC Meds	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.h	8. Cocaine	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.i	Cocaine Route	Pulldown List 3 ⌄
5.j	9. Amphetamine	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.k	Amphetamine Route	Pulldown List 3 ⌄
5.l	10. Methamphetamine	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.m	Methamphetamine Route	Pulldown List 3 ⌄
5.n	11. Opiates	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.o	Opiates Route	Pulldown List 3 ⌄
5.p	12. Sedatives	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.q	13. Hallucinogens	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.r	14. Club Drugs	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.s	15. Inhalant	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.t	Inhalant Specify	[99] ○ A20 [98] ○ NA
5.u	16. Other	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.v*	Other Specify	[99] ○ A20 [98] ○ NA
5.w	Other Route	Pulldown List 3 ⌄

6.	17. Is there a discrepancy between the self-report and today's urine toxicology results?	[98] ○ NA [0] ○ 0 No [1] ○ 1 Yes 17a. If yes, please indicate for which drug(s)

QSTEST

Amphetamine	Barbiturates	Benzos	Cocaine	Methamphetamine	Morphine (opiates)	THC (marijuana)
[0] ○ 0 No	[0] ○ 0 No	[0] ○ 0 No	[0] ○ 0 No	[0] ○ 0 No	[0] ○ 0 No	[0] ○ 0 No
[1] ○ 1 Yes	[1] ○ 1 Yes	[1] ○ 1 Yes	[1] ○ 1 Yes	[1] ○ 1 Yes	[1] ○ 1 Yes	[1] ○ 1 Yes
[98] ○ NA	[98] ○ NA	[98] ○ NA	[98] ○ NA	[98] ○ NA	[98] ○ NA	[98] ○ NA

QSORRES

Item is not required

QSCAT=TREATMENT COMPLIANCE PILL COUNT   **DOMAIN: QS**

CTN0028 : 2841 - Treatment Compliance - Pill Count (TCO) - Repeating Form

#	Assessment Date	Visit Number	Sequence Number	Week assessed	Date Bottle Dispensed	Number pills returned expected	Number pills returned actual	Pills reported lost	Date bottle returned	Replacement medication dispensed	Inconsistentcies between pill count	Date Replacement bottle dispensed	Pills dispensed	Replacement pills returned	Replacement pills actual	Replacement pills lost	Date Replacement bottle returned
1																	

Section I: Scheduled OROS-MPH/Placebo

1.	Assessment Date	**QSDTC**	Req ⌄ / Req ⌄ / Req ⌄ (2005-2008) (mm/dd/yyyy)
2.	Visit Number	**VISITNUM/VISIT**	[99] ○ xxx [98] ○ NA
3.	Sequence Number	**QSTEST**	[99] ○ xx [98] ○ NA
4.	1. Study week being assessed:		[99] ○ xxx [98] ○ NA
5.	2. Date bottle dispensed:		[99] ○ Req ⌄ / Req ⌄ / Req ⌄ (2005-2008) (mm/dd/yyyy) [98] ○ NA
6.	3. Number of pills returned (expected):		[99] ○ xx [98] ○ NA
7.	4. Number of pills returned (actual):		[99] ○ xx [98] ○ NA
8.	5. Number of pills reported lost:		[99] ○ xx [98] ○ NA
9.	6. Date bottle returned:		[99] ○ Req ⌄ / Req ⌄ / Req ⌄ (2005-2008) (mm/dd/yyyy) [98] ○ NA
10.	7. Was replacement medication dispensed?		[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
11.	8. Are there any inconsistencies between pill count and self-reported administration of pills?		[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA

Section II: Replacement OROS-MPH/Placebo

QSORRES

12.	9. Date replacement bottle dispensed:	[99] ○ Req ⌄ / Req ⌄ / Req ⌄ (2005-2008) (mm/dd/yyyy) [98] ○ NA
13.	10. Number of pills dispensed:	[99] ○ xx [98] ○ NA
14.	11. Number of pills returned-expected:	[99] ○ xx [98] ○ NA
15.	12. Number of pills returned - actual:	[99] ○ xx [98] ○ NA
16.	13. Number of pills reported lost:	[99] ○ xx [98] ○ NA
17.	14. Date replacement bottle returned:	[99] ○ Req ⌄ / Req ⌄ / Req ⌄ (2005-2008) (mm/dd/yyyy) [98] ○ NA

QSCAT=MEDICATION LIKING   DOMAIN: QS

	CTN0028 : 2829 - Medication Liking (MLI)	
1.	Assessment Date **QSDTC**	Req / Req / Req (2005-2008) (mm/dd/yyyy)
2.	Visit Number **VISITNUM/VISIT**	[99] ○ xxx [98] ○ NA
	For each question, please fill in the circle below the number that best represents how you feel **QSTEST**	**QSORRES**
3.	1. Do you feel that your medication has been effective in treating your ADD/ADHD symptoms?	Pulldown List 1 ▼ not at all = 1 / somewhat = range 5-6 / very much = 10
4.	2. Do you like the way your medication makes you feel?	Pulldown List 2 ▼ not at all = 1 / somewhat = range 5-6 / very much = 10
5.	3. When you take your medication, how high/ euphoric feeling do you get?	Pulldown List 3 ▼ not at all = 1 / sometimes high/euphoric feeling = range 5-6 / very high/euphoric feeling = 10
6.	4. When you take your medication, how depressed/ down feeling do you get?	Pulldown List 4 ▼ not at all = 1 / sometimes depressed feeling = range 5-6 / very depressed/down feeling = 10
7.	5. Do you ever crave your medication?	Pulldown List 5 ▼ not at all = 1 / sometimes = range 5-6 / very frequently = 10
8.	6. When you take your medication, do you ever crave cigarettes, alcohol, or other drugs?	Pulldown List 6 ▼ not at all = 1 / sometimes = range 5-6 / very frequently = 10
9.	7. When you take your medication, how physically active do you feel compared to what is normal for you?	Pulldown List 7 ▼ much less active = 1 / about the same = range 5-6 / much more active = 10

QSCAT=MGH MEDICATION QUESTIONNAIRE   **DOMAIN: QS**

	CTN0028 : 2830 - MGH Medication Questionnaire (MGH)	
1.	Assessment Date **QSDTC**	Req / Req / Req (2005-2008) (mm/dd/yyyy)
2.	Visit Number **VISITNUM/VISIT**	[99] ○ xxx [98] ○ NA
	The following questions refer to the medication that you are taking in this study. **QSTEST** **QSORRES**	
3.	1. Do you remember to take your medication?	[1] ○ 1 Always [2] ○ 2 Mostly [3] ○ 3 Sometimes [4] ○ 4 Rarely [98] ○ NA
4.	2. Do you think your medication helps you?	[1] ○ 1 Always [2] ○ 2 Mostly [3] ○ 3 Sometimes [4] ○ 4 Rarely [98] ○ NA
5.	1. Have you ever sold your medication to others?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA
6.	2. Have you let others take your medication (e.g., friends, family members, etc.)?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA
7.	3. Have you taken more of your medication than you were supposed to?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA
8.	4. Have you gotten high on your medication?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA
9.	5. Have you taken your medication in other ways than prescribed?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA
10.	6. Have you not taken your medication so that you could use drugs or alcohol?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA
11.	7. Have you used alcohol or drugs on the days you take your medication?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA
12.	8. Have you had a reaction to drugs or alcohol while taking your medication?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA

QSCAT=CLINICIAN GLOBAL IMPRESSION OF IMPROVEMENT (CGI)   DOMAIN: **QS**

	CTN0028 : 2831-Clinician Global Impression of Improvement (CGI-I) - ADHD (CGI)		
1.	Assessment Date QSDTC	Req ▾ / Req ▾ / Req ▾ (2005-2008) (mm/dd/yyyy)	
2.	Visit Number VISITNUM/VISIT	[99] ○ xxx [98] ○ NA	
	Global improvement - Rate the participant's level of improvement by considering the participant's current ADHD symptoms compared to his or her symptoms at baseline. Rate total improvement whether or not, in your judgment, it is due entirely to drug treatment.		
3.	1. Compared to his/her condition at screening/baseline, how much has he/she changed? QSTEST	Pulldown List 1 ▾	QSORRES

QSCAT=CHECK ON BLIND ADOLESCENT (CBA)   DOMAIN: **QS**

	CTN0028 : 2832 - Check on Blind Adolescent (CBA)	
1.	Assessment Date QSDTC	Req / Req / Req (2005-2008) (mm/dd/yyyy)
2.	Visit Number VISITNUM/VISIT	[99] ○ xxx [98] ○ NA
3.	1. As a participant in this study, you have been taking either OROS-MPH or Placebo (sugar) pills. Which kind of pill do you think you have been taking? ← QSTEST	[1] ○ 1 OROS-MPH [2] ○ 2 Placebo (sugar) [98] ○ NA ← QSORRES
4.	2. How confident are you that your selection for question 1 is actually the type of pills that you have been taking?	Pulldown List 1 ▾

QSCAT=MEDICATION BLIND ASSESSMENT (MBA)   DOMAIN: QS

CTN0028 : 2833 - Medication Blind Assessment - MC (MBA)	
1. Assessment Date QSDTC	[Req ▼] / [Req ▼] / [Req ▼] (2005-2008) (mm/dd/yyyy)
2. Visit Number VISITNUM/VISIT	[99] ○ xxx [98] ○NA
3. 1. This participant has been taking either OROS-MPH or placebo (sugar) pills. Which kind of pills do you think the participant has been taking? ← QSTEST	[1] ○1 OROS-MPH [2] ○2 Placebo (sugar) ← QSORRES [98] ○NA
4. 2. How confident are you that your selection for question 1 is actually the type of pills that the participant has been taking?	[1] ○1 Not at all confident [2] ○2 Mildly confident [3] ○3 Moderately confident [4] ○4 Quite confident [5] ○5 Very confident 3. If you selected "Very Confident" in response to question 2, what is the basis for your confidence? [1] ○1 My observation of the participant's response to the medication [2] ○2 Information about the patient's treatment assignment (e.g., accidentally saw paperwork, blind broken for medical purposes, etc.) [3] ○3 Other (specify): A200 [98] ○NA [98] ○NA

QSCAT=TLFB ACTIVE STUDY (TLA)   **DOMAIN: QS**

CTN0028 : 2834 - TLFB - Active Study (TLA) - Repeating Form

#	Assessment Date	Visit Number	Sequence Number	Primary Drug	Drug Informati
1					

1.	Assessment Date	NReq / NReq / NReq (2005-2008) (mm/dd/yyyy) **QSDTC**
2.	Visit Number	[99] ○ xxx [98] ○ NA **VISITNUM/VISIT**
3.	Sequence Number	[99] ○ xx [98] ○ NA
4.	1. Primary Drug	Pulldown List 1 Specify other A50 **QSTEST** **QSORRES**

SEQUENCE NUMBER NOT USED. GENERATED SEQUENCE NUMBER FROM DATA INSTEAD (SEE EXSEQ)

	Day	Date	Alcohol standard drinks	Marijuana joints	Cigarettes cpd	Other Tobac	OTC Meds	Cocaine	Cocaine Route	Amphetamine	Amp Rou
5.											

Drug Information Entry   **QSTEST**   **QSORRES**

5.a	Day	Pulldown List 2
5.b	2. Date	[99] ○ Req / Req / Req (2005-2008) [98] ○ NA
5.c	3. Alcohol	[99] ○ # Stnd Drinks xxx [98] ○ NA
5.d	4. Marijuana	[99] ○ # jnts xxx [98] ○ NA
5.e	5. Cigarettes	[99] ○ # cpd xxx [98] ○ NA
5.f	6. Other Tobac	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.g	7. OTC Meds	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.h	8. Cocaine	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.i	Cocaine Route	Pulldown List 3
5.j	9. Amphetamine	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.k	Amphetamine Route	Pulldown List 3
5.l	10. Methamphetamine	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.m	Methamphetamine Route	Pulldown List 3
5.n	11. Opiates	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.o	Opiates Route	Pulldown List 3
5.p	12. Sedatives	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.q	13. Hallucinogens	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.r	14. Club Drugs	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.s	15. Inhalant	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.t	Inhalant Specify	[99] ○ A20 [98] ○ NA
5.u	16. Other	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
5.v*	Other Specify	[99] ○ A20 [98] ○ NA
5.w	Other Route	Pulldown List 3

QSTEST   **QSORRES**

6.	17. Is there a discrepancy between the self-report and today's urine toxicology results?	[98] ○ NA [0] ○ 0 No [1] ○ 1 Yes 17a, If yes, please indicate for which drug(s)

Amphetamine [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
Barbiturates [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
Benzos [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
Cocaine [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
Methamphetamine [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
Morphine (opiates) [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
THC (marijuana) [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA

QSTEST

QSORRES

Item is not required

QSCAT=TREATMENT STATUS AT FOLLOW-UP   **DOMAIN: QS**

	CTN0028 : 2842 - Treatment Status at Follow-up (TSF)	
1.	Assessment Date QSDTC	Req / Req / Req (2005-2008) (mm/dd/yyyy)
2.	Visit Number VISITNUM/VISIT	[99] ○ xxx [98] ○ NA
I. ADHD QSSCAT=ADHD		
3.	1. Has the patient utilized any treatment for his or her ADHD since completing the active study? QSTEST	[0] ○ 0 No [1] ○ 1 Yes a.1 Medication Utilitzed since completing active study? Currently Utilizing? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA a.2 Psychosocial Utilitzed since completing active study? Currently Utilizing? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA [98] ○ NA QSORRES
4.	2. Does the participant plan to seek treatment for his or her ADHD?	[0] ○ 0 No [1] ○ 1 Yes What type of treatment is he or she planning to seek? a.1 Medication [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA a.2 Psychosocial [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA [98] ○ NA
II. SUD QSSCAT=SUD		
5.	3. Has the participant utilized and treatment for his or her SUD since completing the active study?	[0] ○ 0 No [1] ○ 1 Yes a.1 Medication Utilitzed since completing active study? Currently Utilizing? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA a.2 Psychosocial Utilitzed since completing active study? Currently Utilizing? [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA [98] ○ NA
6.	4. Does the participant plan to seek treatment for his or her SUD?	[0] ○ 0 No [1] ○ 1 Yes What type of treatment is he or she planning to seek? a.1 Medication [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA a.2 Psychosocial [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA [98] ○ NA

DOMAIN: AE, SUPPAE

AECAT = AE

CTN0028 : 2824 - Adverse Events Form (AEF) - Repeating Form

#	Assessment Date	Visit Number	Sequence Number	Any new AE\'s	AE Name/Description	Type of Report	Visit	Sequence	Date of Onset	Study Drug Related	Severity	Action taken	Other Action Taken (1)	Other Action Taken (2)	Other Action Taken (3)	Other Action Taken (4)	Other Action Taken (5)	Other actions/comments	Serious Adverse Event	Outcome	Visit on which AE Assessed (01)	Visit on which AE Assessed (02)	Visit on which AE Assessed (03)	Visit on which AE Asse (0
1																								

1.	Assessment Date	**AEDTC**	[Req▼] / [Req▼] / [Req▼] (2005-2008) (mm/dd/yyyy)
2.	Visit Number	See below for VISIT	[99] ○ xxx [98] ○ NA
3.	Sequence Number	**AESPID**	[99] ○ xx [98] ○ NA

NOTE: if 0 or 98 checked for item 1, then form is dropped

4.	1. Did the participant have any new adverse events or severity changes in previously reported AEs...	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA If No or NA, Please check NA for the rest of the questions on the form.
5.	2. Adverse Event Name/Description:	**AETERM**	[99] ○ A100 [98] ○ NA
6.	3.a Type of Report:	[1] ○ 1 New Adverse Event [2] ○ 2 Change in severity of an existing Adverse Event [98] ○ NA
7.	3.b If there is a change in severity report (3.a=2), then record the Visit# and Sequence# of the prior AE	[99] ○ 3.b Visit #: xxx [98] ○ NA
8.	3.c Sequence #:	**NOT USED, REPEAT OF 3 ABOVE**	[99] ○ 3.c xx [98] ○ NA
9.	4. Date of onset (or change) of event (mm/dd/yyyy)	**AESTDTC**	[99] ○ [Req▼] / [Req▼] / [Req▼] (2005-2008) [98] ○ NA
10.	5. Study Drug Related	**AEREL**	Pulldown List 1 ▼
11.	6. Severity	**AESEV**	Pulldown List 2 ▼
12.	7. Action Taken Regarding Study Drug	**AEACN**	Pulldown List 3 ▼
13.	8a.1 Other Action Taken?	[1] ○ 1 None [98] ○ NA
14.	8a.2 Other Action Taken?	[2] ○ 2 Remedial Therapy - pharmacologic [98] ○ NA
15.	8a.3 Other Action Taken?	[3] ○ 3 Remedial Therapy - non-pharmacologic [98] ○ NA
16.	8a.4 Other Action Taken?	[4] ○ 4 Hospitalization (new or prolonged) [98] ○ NA
17.	8a.5 Other Action Taken?	[5] ○ 5 Other [98] ○ NA

AEACNOTH

18.	8b. Description of other actions or comments:	[99] ○ A200 [98] ○ NA
19.	09. Was the Adverse Event Serious? (If Yes, you must complete an SAE form and report it correctly)	**AESER**	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA
20.	10. Outcome	**AEOUT**	Pulldown List 4 ▼
21.	11.1 Visit on which AE assessed	[1] ○ 01 [98] ○ NA
22.	11.2 Visit on which AE Assessed	[2] ○ 02 [98] ○ NA
23.	11.3 Visit on which AE Assessed	[3] ○ 03 [98] ○ NA
24.	11.4 Visit on which AE Assessed	[4] ○ 04 [98] ○ NA
25.	11.5 Visit on which AE Assessed	[5] ○ 05 [98] ○ NA
26.	11.6 Visit on which AE Assessed	[6] ○ 06 [98] ○ NA
27.	11.7 Visit on which AE Assessed	[7] ○ 07 [98] ○ NA
28.	11.8 Visit on which AE Assessed	[8] ○ 08 [98] ○ NA
29.	11.9 Visit on which AE Assessed	[9] ○ 09 [98] ○ NA
30.	11.10 Visit on which AE Assessed	[10] ○ 10 [98] ○ NA
31.	11.11 Visit on which AE Assessed	[11] ○ 11 [98] ○ NA
32.	11.12 Visit on which AE Assessed	[12] ○ 12 [98] ○ NA
33.	11.13 Visit on which AE Assessed	[13] ○ 13 [98] ○ NA

One record was output for each AE for each VISIT/VISITNUM that was checked for questions 11.1 though 12.

QNAM=AERPTTYP
 QLABEL=AE TYPE OF REPORT
 IDVAR=AESEQ

QNAM=VISNUMC
 QLABEL=VISIT # OF CHANGE
 IDVAR=AESEQ

QNAM=DESACT
 QLABEL=DESCRIPTION OF ACTION TAKEN
 IDVAR=AESEQ

DOMAIN: **AE**

34.	11.14 Visit on which AE Assessed	*[14]* ○ 14 *[98]* ○ NA
35.	11.15 Visit on which AE Assessed	*[15]* ○ 15 *[98]* ○ NA
36.	11.16 Visit on which AE Assessed	*[16]* ○ 16 *[98]* ○ NA
37.	11.17 Visit on which AE Assessed	*[17]* ○ 17 *[98]* ○ NA
38.	12. Visit on which Outcome (see question 10) recorded	**[99]** ○ xxx *[98]* ○ NA
39.	13. Date of resolution or change in severity? AEENDTC	**[99]** ○ Req ▾ / Req ▾ / Req ▾ (2005-2008) (mm/dd/yyyy) *[98]* ○ NA

AECAT = SAE

SUPPAE

CTN0028 : 2825 - Serious Adverse Events (SAE1) - Repeating Form

#	Assessment Date	Visit Number	Seq Num	AE Visit #	AE Seq #	SAE Report Type	SAE Name	SAE Description	SAE Onset Date	SAE Resolution Date	Death	Life Threatening	Hospitalization	Disability	Congenital Anomaly	Intervention	Severity	Relationship	Action Taken	Outcome	Date of Death	Investigational Agent Information	Name
1																							

An AE form must be submitted for this event

1.	Assessment Date	Req / Req / Req (2005-2008) (mm/dd/yyyy)	AEDTC
2.	Visit Number	[99] ○ xxx [98] ○ NA	VISITNUM/VISIT
3.	Sequence Number	xx	AESPID
4.	AE Visit #	xxx	AEGRPID
5.	AE Sequence Number	xx	AEGRPID
6.	1. SAE Report Status	Pulldown List 1	
7.	2. SAE Name (name of event)	[99] ○ A200 [98] ○ NA	AETERM
8.	3. SAE Description	[99] ○ A200 [98] ○ NA	
9.	4. SAE Onset Date	[99] ○ Req / Req / Req (2005-2008) (mm/dd/yyyy) [98] ○ NA	AESTDTC
10.	5. SAE Resolution Date	[99] ○ Req / Req / Req (2005-2008) (mm/dd/yyyy) [98] ○ NA	AEENDTC
11.	SAE Categorization - 6.a Death	[1] ○ 1 Yes [0] ○ 0 No	AESDTH
12.	6.b Life Threatening	[1] ○ 1 Yes [0] ○ 0 No	AESLIFE
13.	6.c Hospitalization (initial or prolonged)	[1] ○ 1 Yes [0] ○ 0 No	AESHOSP
14.	6.d Disability	[1] ○ 1 Yes [0] ○ 0 No	AESDISAB
15.	6.e Congenital Anomaly	[1] ○ 1 Yes Pulldown List 2 [0] ○ 0 No	AESCONG
16.	6.f Required Intervention to Prevent One of the Above Outcomes	[1] ○ 1 Yes [0] ○ 0 No	
17.	7. Severity of SAE	Pulldown List 3	AESEV
18.	8. Relationship to Study Agent	[1] ○ 1 Definitely [2] ○ 2 Probably [3] ○ 3 Possibly [4] ○ 4 Unrelated [98] ○ NA	AEREL
19.	9. SAE Actions Taken	Pulldown List 4	AEACN
20.	10. SAE Outcome	[1] ○ 1 Recovered/resolved [2] ○ 2 Recovered or resolved with sequelae [3] ○ 3 Not recovered/not resolved [4] ○ 4 Fatal [98] ○ NA	AEOUT
21.	11. Date of Death	[99] ○ Req / Req / Req (2005-2008) (mm/dd/yyyy) [98] ○ NA	

Please complete the investigational data fields below (Note: 12a should be answered NA if blind still intact)

22.	12. Is the investigational agent information known?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA	
23.	12a. Investigational Agent Name (if known)	[99] ○ A50 [98] ○ NA	
24.	12b. Investigational Agent Lot Number	[99] ○ A22 [98] ○ NA	
25.	12c. Investigational Agent Expiration Date	[99] ○ Req / Req (2005-2008) (mm/dd/yyyy) month / year [98] ○ NA	
26.	12d. Quantity of Investigational	NA	SEE NEXT PAGE

Annotations (red):

QNAM=AEREPORT
QLABEL=SAE REPORT STATUS
IDVAR=AESEQ

QNAM=SAEDESCR
QLABEL=SAE DESCRIPTION
IDVAR=AESEQ

QNAM=SAEINTV
QLABEL=REQUIRED INTERVENTION TO PREVENT OUTCOME
IDVAR=AESEQ

QNAM=AEDTHDT
QLABEL=DATE OF DEATH
IDVAR=AESEQ

QNAM=AEINFKNW
QLABEL=INVEST AGENT INFO KNOWN
IDVAR=AESEQ

QNAM=AEAGNTNM
QLABEL=AGENT NAME
IDVAR=AESEQ

QNAM=AEEXPDTE
QLABEL=EXPIRATION DATE
IDVAR=AESEQ

QNAM=AELOTNO
QLABEL=AGENT LOT NUMBER
IDVAR=AESEQ

	Agent Administered	**[99]** ○ | xxx | *[98]* ○	
27.	12e. Start Date	**[99]** ○ |Req ▾| / |Req ▾| / |Req ▾| (2005-2008) (mm/dd/yyyy) *[98]* ○NA	
28.	12f. Date Last Administered	**[99]** ○ |Req ▾| / |Req ▾| / |Req ▾| (2005-2008) (mm/dd/yyyy) *[98]* ○NA	
29.	12g. Investigational Agent Dosage	Pulldown List 5 ▾	
30.	12h. Dosage Form	Pulldown List 6 ▾	
31.	12i. Administration Frequency	Pulldown List 7 ▾	
32.	12j. Route of Administration	Pulldown List 8 ▾	
33.	13. Relevant tests/laboratory data, including dates	**[99]** ○ A200 *[98]* ○NA	

QNAM=AEQNTADM
QLABEL=QUANTITY OF AGENT ADMINISTERED
IDVAR=AESEQ

QNAM=AESRTDTE
QLABEL=START DATE
IDVAR=AESEQ

QNAM=AELSTADM
QLABEL=DATE LAST ADMINISTERED
IDVAR=AESEQ

QNAM=AEDOSAGE
QLABEL=INVESTIGATIONAL AGENT DOSAGE
IDVAR=AESEQ

QNAM=AEDOSFRM
QLABEL=DOSAGE FORM
IDVAR=AESEQ

QNAM=AEADMFRQ
QLABEL=ADMINISTRATION FREQUENCY
IDVAR=AESEQ

QNAM=AERTEADM
QLABEL=ROUTE OF ADMINISTRATION
IDVAR=AESEQ

QNAM=AERELTES
QLABEL=RELEVANT TESTS ADMINISTERED
IDVAR=AESEQ

DOMAIN: **CM**

CTN0028 : 2825 - Serious Adverse Events Concomitant Drug (SAE2) - Repeating Form

#		Concomitant Drug Therapy	
1	⚇	CMCAT = 'SAE CONCOMITANT DRUGS'	

	Visit Number	Seq Num	AE Visit #	AE Seq #	Drug	Quantity	Dosage Units	Dosage Form	Route	Administration Frequency
1.										

Concomitant Drug Therapy Entry

1.a	Visit Number	Not entered	[99] ○ xxx [98] ○NA
1.b	Sequence Number		xx
1.c	AE Visit #		xxx
1.d	AE Sequence Number		xx
1.e	14a. Drug (include generic name)	CMTRT	ASO
1.f	14b. Quantity per Administration	CMDOSE	[99] ○ xx [98] ○NA
1.g	14c. Dosage Units	CMDOSU	Pulldown List 1 ▾
1.h	14d. Dosage Form	CMDOSFRM	Pulldown List 2 ▾
1.i	14e. Route of Administration	CMROUTE	Pulldown List 3 ▾
1.j	14f. Administration Frequency	CMDOSFRQ	Pulldown List 4 ▾

QNAM=AEVIS
QLABEL=RELATED AE VISIT NUMBER
IDVAR=CMSEQ

QNAM=AEREF
QLABEL=RELATED AE FORM SEQUENCE NUMBER
IDVAR=CMSEQ

DATA NOT ENTERED

CTN0028 : 2825 - Serious Adverse Events Contd (SAE2B) - Repeating Form

#		Visit Number	Seq Num	AE Visit #	AE Seq #	Relevant History	Comments	Name	Phone Number	Email	Reporters Name	Site M.D. Name	Medical Monitor
1	⊠												

SAE Contd

1.	Visit Number	[99] ◯ xxx [98] ◯ NA
2.	Sequence Number	| xx |
3.	AE Visit #	| xxx |
4.	AE Sequence Number	| xx |
5.	15. Relevant history, including date of consent and pre-existing medical conditons (e.g. allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)	A200
6.*	16. Additonal Comments	A200

17. Address SAE question to the following Clinical Staff:

7.	17a. Name (print)	A50
8.	17b. Phone Number	A20
9.	17c.Email	A50
10.	17d. SAE Reporters Name (please print)	A50
11.	17e. Site M.D. Name	A50
12.	17g. Study Medical Monitor Name	A50

* Item is not required

QSCAT=PARTICIPANT STATUS AT END OF ACTIVE TRIAL   **DOMAIN: QS**

CTN0028 : 2836 - Participant Status at End of Active Trial (PST)	
1.	Assessment Date **QSDTC**	Req ▾ / Req ▾ / Req ▾ (2005-2008) (mm/dd/yyyy)
2.	Visit Number **VISITNUM/VISIT**	[99] ○ xxx [98] ○ NA
3.	1. Date last research visit attended: **QSTEST**	[99] ○ Req ▾ / Req ▾ / Req ▾ (2005-2008) (mm/dd/yyyy) [98] ○ NA **QSORRES**
4.	2. How many CBT sessions were offered to the participant?	[99] ○ xxx [98] ○ NA
5.	3. How many CBT sessions did the participant attend?	[99] ○ xxx [98] ○ NA
6.	4. Please indicate the participant's status at the end of his or her participation in the active study phase:	Pulldown List 1 ▾ 4a. Specify (for Administrative Discharge or Other): A200
7.	5.a Does the study staff recommend that the participant seek treatment for his or her ADHD?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA If yes, what type of treatment is recommended? 5.a.1 Medication [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA 5.a.2 Psychosocial [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
8.	6.a Does the particiapant plan to seek treatment for his or her ADHD?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA If yes, what type of treatment is he or she planning to seek? 6.a.1 Medication [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA 6.a.2 Psychosocial [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
9.	7.a Does the styudy staff recommend that the participant seek treatment for his or her SUD?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA If yes, what type of treatment is recommended? 7.a.1 Medication [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA 7.a.2 Psychosocial [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
10.	8.a Does the participant plan to seek treatment for his or her Substance Use Disorder?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA If yes, what type of treatment is he or she planning to seek? 8.a.1 Medication [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA 8.a.2 Psychosocial [0] ○ 0 No [1] ○ 1 Yes [98] ○ NA

QSCAT=CBT FIDELITY RATING FORM-INDIVIDUAL SESSION (CBT2)   **DOMAIN: QS**

CTN0028 : 2837-CBT Fidelity Rating Form - Individual Session (CBT2) - Repeating Form

#	Assessment Date	Visit Number	Clinician ID	Supervisor ID	Session Date	Type of Review	CBT Module	Clinician review at-home	Clinician assess use of substances	Clinician elicit participation	Clinician teach and model	Clinician involve participant	Clinician keep session focused	Therapist develop practice assignments	Comments
1															

1.	Assessment Date	**QSDTC**	Req ▾ / Req ▾ / Req ▾ (2005-2008) (mm/dd/yyyy)
2.	Visit Number **VISITNUM/VISIT**		[99] ○ xxx [98] ○ NA
3.	1. Clinician ID:	**QSTEST**	[99] ○ xxxxx [98] ○ NA **QSORRES**
4.	2. Supervisor ID:		[99] ○ xxxxx [98] ○ NA
5.	3. Session Date:		[99] ○ Req ▾ / Req ▾ / Req ▾ (2005-2008) [98] ○ NA
6.	4. Type of Review:		[1] ○ 1 Interventionist Fidelity [2] ○ 2 Interventionalist Certification [3] ○ 3 Other 　　Type of Review, Other: 　　| A50 [98] ○ NA
7.	5. CBT Module:		Pulldown List 1 ▾
8.	6. To what extent did the clinician review the participant's *at-home practice* and, as necessary, address any difficulties in carrying out the assignment; provide a reminder of the rationale and importance of extra-session practice; and give an opportunity to complete during session if it was not done?		Pulldown List 2 ▾
9.	7. To what extent did the clinician *assess the participant's use of substances* since the last session including exploring *high-risk situations* s/he encountered?		Pulldown List 3 ▾
10.	8. To what extent did the clinician *elicit participation* in selecting one specific session topic and *provide a rationale* to the participant for why these skills are being covered during this session?		Pulldown List 4 ▾
11.	9. To what extent did the clinician *teach and model* specific skills (e.g. explaining new skill step-by-step using relevant examples from the participant's life)?		Pulldown List 5 ▾
12.	10. To what extent did the clinician involve the participant in the in-session practice in order to *rehearse* the new skills learned (e.g. behavior rehearsal role plays or other relevant practice exercises as suggested in the intervention manual)?		Pulldown List 6 ▾
13.	11. To what extent did the clinician *keep the session focused* on prescribed activities (e.g. by redirecting dialogue when it strayed off task and by organizing the session so defined tasks were covered) and balance this with maintaining an empathic listening style?		Pulldown List 7 ▾
14.	12. To what extent did the therapist develop one or more specific and realistic *at-home practice assignments* for the participant to engage in between sessions and explain how to do this to the participant?		Pulldown List 8 ▾
15.*	13. Comments:		A200

* Item is not required

QSCAT=CBT FIDELITY RATING FORM-FAMILY SESSION (CBF2)

DOMAIN: QS

CTN0028 : 2838 - CBT Fidelity Rating Form - Family Session (CBF2) - Repeating Form

#	Assessment Date	Visit Number	Clinician ID	Supervisor ID	Session Date	Type of Review	CBT Module	Clinician Explain and Answer	Clinician review progress	Clinician elicit participation	Clinician teach and model	Clinician involve all attendees	Clinician keep session focused	Clinician develop practice assignments	Comments
1															

1.	Assessment Date	QSDTC	Req ⌄ / Req ⌄ / Req ⌄ (2005-2008) (mm/dd/yyyy)
2.	Visit Number	VISITNUM/VISIT	[99] ○ xxx [98] ○ NA
3.	1. Clinician ID:	QSTEST	[99] ○ xxxxx [98] ○ NA QSORRES
4.	2. Supervisor ID:		[99] ○ xxxxx [98] ○ NA
5.	3. Session Date:		[99] ○ NReq ⌄ / Req ⌄ / Req ⌄ (2005-2008) [98] ○ NA

6.	4. Type of Review:		[1] ○ 1 Interventionist Fidelity
			[2] ○ 2 Interventionalist Certification
			[3] ○ 3 Other
			    Type of Review, Other:
			    | A50
			[98] ○ NA

7.	5. CBT Module:		[1] ○ 1 15-1 Family Session #1 (SV 4/5) [2] ○ 2 15-2 Family Session #2 (SV 9/10) [3] ○ 3 15-3 Family Session #3 (SV 14/15) [98] ○ NA
8.	6. To what extent did the clinician *explain and answer questions about the therapy process* to the family and/or other attendees (including specifics about substance use, cognitive-behavioral therapy for substance use, and skills learned to be taught during the therapy)?		Pulldown List 1 ⌄
9.	7. To what extent did the clinician *review the participant's progress in therapy* with the family and/or other attendees using positive language and motivational enhancement strategies?		Pulldown List 2 ⌄
10.	8. To what extent did the clinician *elicit participation* from all attendees including the study participant in selecting at least one topic or issue on which to focus during the session?		Pulldown List 3 ⌄
11.	9. To what extent did the clinician *teach and model* positive communication and problem-solving skills to the family or other attendees using real-life examples whenever possible?		Pulldown List 4 ⌄
12.	10. To what extent did the clinician involve all attendees in the *practice of new skills taught*?		Pulldown List 5 ⌄
13.	11. To what extent did the clinician *keep the session focused* on prescribed activities (e.g. by redirecting dialogue when it strayed off task and by organizing the session so defined tasks were covered) and balance this with maintaining an empathic listening style?		Pulldown List 6 ⌄
14.	12. To what extent did the clinician develop one or more specific and realistic *at-home practice assignments* for the family participants to engage in between sessions and explain how to do this to everyone involved?		Pulldown List 7 ⌄
15.*	13. Comments:		A200

* Item is not required

QSCAT=CLINICAL TREATMENT SESSION SUMMARY FAMILY (CSS)　　　**DOMAIN: QS**

#	Assessment Date	Visit Number	CBT Module	Since last session	Appointments were scheduled	Client no show	Client cancel	Appointments cancelled	Today's session	Session Participants	Record and label audiotape	Problems coordinator should know	Explain and answer questions	Review participant's progress	Elicit participation from attendees	Teach and model communication	Involve attendees in practice	Keep the session focused	Develop at-home assignments
1																			

CTN0028 : 2840-CBT Clinician Treatment Session Summary - Family (CSS) - Repeating Form

1.	Assessment Date	**QSDTC**	Req / Req / Req (2005-2008) (mm/dd/yyyy)
2.	Visit Number	**VISITNUM/VISIT**	[99] ○ xxx [98] ○ NA

1. Session Information

| 3. | 1. CBT Module: | **QSTEST** | [1] ○ 1 15-1 Family Session #1 (SV 4/5)
[2] ○ 2 15-2 Family Session #2 (SV 9/10)
[3] ○ 3 15-3 Family Session #3 (SV 14/15)
[98] ○ NA | **QSORRES** |

A. Activity Since Last Session
Since the last session (or since randomization for the first session):

4.	2. How long has it been since your last session?	[99] ○ xx (days) [98] ○ NA
5.	3. How many appointments were scheduled since the last session?	[99] ○ xx [98] ○ NA
6.	4. How many appointments did the client no show to?	[99] ○ xx [98] ○ NA
7.	5. How many appointments did the client cancel?	[99] ○ xx [98] ○ NA
8.	6. How many appointments did you cancel?	[99] ○ xx [98] ○ NA

B. Information About Today's Session

9.	7. How long was today's session? (in minutes)	[99] ○ xxx [98] ○ NA
10.	8. Session Participants (select all that apply):	[98] ☐ NA [1] ☐ Mother [2] ☐ Father [3] ☐ Stepmother [4] ☐ Stepfather [5] ☐ Brother [6] ☐ Sister [7] ☐ Boyfriend [8] ☐ Girlfriend [9] ☐ Friend [10] ☐ Teacher [11] ☐ Legal office [12] ☐ Other Relative | A20 (8.a Specify): [13] ☐ Other Non-Relative | A20 (8.b Specify):
11.	9. Did you record and label the audiotape with your ID, the participant's ID, study week, the session topic, and date?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA
12.	10. Are there problems the investigators or coordinator should know about?	[1] ○ 1 Yes [0] ○ 0 No [98] ○ NA

II. Treatment Adherence Checklist

13.	1. To what extent did you explain and answer questions about the therapy process to the family and/or other attendees (including specifics about substance use, cognitive-behavior therapy for substance use, and skills learned and to be taught during the therapy)?	Pulldown List 1 ▾
14.	2. To what extent did you review the participant's progress in therapy with the family and/or other attendees using positive language and motivational enhancement strategies?	Pulldown List 2 ▾
15.	3. To what extent did you elicit participation from all attendees including the study participant in selecting at least one topic or issue on which to focus during the session?	Pulldown List 3 ▾
16.	4. To what extent did you teach and model positive communication and problem-solving skills to the family or other attendees using real-life examples whenever possible?	Pulldown List 4 ▾
17.	5. To what extent did you involve all attendees in the practice of new skills taught (e.g. behavior rehearsal role plays or other relevant practice exercises as suggested in the intervention manual)?	Pulldown List 5 ▾
18.	6. To what extent did you keep the session focused on prescribed activities (e.g. by redirecting dialogue when it strayed off task and by organizing the session so defined tasks were covered) and balance this with maintaining an	Pulldown List 6 ▾

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	empathic listening style?	
19.	7. To what extent did you develop one or more specific and realistic at-home practice assignments for the family participants to engage in between sessions and explain how to do this with everyone involved?	Pulldown List 7 ▾

QSCAT=PREGNANCY AND OUTCOME   DOMAIN: **QS**

	CTN0028 : 2844 - Pregnancy and Outcome (POC)	
1.	Assessment Date QSDTC	Req ▾ / Req ▾ / Req ▾ (2005-2008) (mm/dd/yyyy)
2.	Visit Number VISITNUM/VISIT	[99] ○ xxx [98] ○ NA
	Section I: Information about Pregnancy QSTEST QSORRES	
3.	1. Who discovered the pregnancy?	[1] ○ 1 Study Participant [2] ○ 2 Study Staff [98] ○ NA
4.	2. How was the pregnancy verified?	[99] ○ (Select all that apply) [1] ☐ 1 Urine Pregnancy Test [2] ☐ 2 Serum Pregnancy Test [3] ☐ 3 Ultrasound [98] ○ NA
5.	3. Date on which the pregnancy was verified:	[99] ○ Req ▾ / Req ▾ / Req ▾ (2005-2008) (mm/dd/yyyy) [98] ○ NA
6.	4. Date on which study staff was aware of pregnancy:	[99] ○ Req ▾ / Req ▾ / Req ▾ (2005-2008) (mm/dd/yyyy) [98] ○ NA
7.	5. Date on which study medication was discontinued:	[99] ○ Req ▾ / Req ▾ / Req ▾ (2005-2008) (mm/dd/yyyy) [98] ○ NA
8.	6. Approximate due date:	[99] ○ Req ▾ / Req ▾ / Req ▾ (2005-2008) (mm/dd/yyyy) [98] ○ NA
	Section II: Outcome of Pregnancy	
9.	7. Outcome of Pregnancy:	[1] ○ 1 Normal [2] ○ 2 Abnormal 7.a If Abnormal Outcome, specify abnormality: A100 [3] ○ 3 Miscarriage [4] ○ 4 Terminated [5] ○ 5 Other 7.b If Other, Outcome, specify other: A100 [98] ○ NA
10.	8. Date of Delivery:	[99] ○ NReq ▾ / Req ▾ / Req ▾ (2005-2008) (mm/dd/yyyy) [98] ○ NA
11.	9. Number of live births - *this pregnancy*?	[0] ○ 0 9.a If 0 live births, indicate reason: [1] ○ 1 [2] ○ 2 [3] ○ 3 [98] ○ NA A100
12.	10. Type of Delivery	[1] ○ 1 Vaginal [2] ○ 2 Cesarean Section [98] ○ NA

QSCAT=PREGNANCY AND OUTCOME CONTINUED   **DOMAIN: QS**

CTN0028 : 2844 - Pregnancy and Outcome Contd (POC NB)												
1.	Assessment Date	QSDTC Req / Req (2005-2008) (mm/dd/yyyy)							QSORRES			
2.	Visit Number VISITNUM/VISIT	[99] ○ xxx [98] ○ NA QSTEST										
	Gender	Weeks	Days	Lbs	Ozs	Length	Circumference	APGAR Score: 1 min	APGAR Score: 5 min	APGAR Score: 24 hrs	Normal	Specify	Contributing factors
3.												

Newborn Information Entry		
3.a	Gender	[1] ○ 1 Male [2] ○ 2 Female [98] ○ NA
3.b	Gestational age at delivery: Weeks	[99] ○ xx Weeks [98] ○ NA
3.c	Gestional age at delivery: Days	[99] ○ x Days [98] ○ NA
3.d	Weight: lbs	[99] ○ xx lbs [98] ○ NA
3.e	Weight: ozs	[99] ○ xx ozs [98] ○ NA
3.f	Length	[99] ○ xx cm [98] ○ NA
3.g	Head circumference	[99] ○ xx cm [98] ○ NA
3.h	APGAR Score: 1 min	[99] ○ xx 1 min [98] ○ NA
3.i	APGAR Score: 5 min	[99] ○ xx 5 min [98] ○ NA
3.j	APGAR Score: 24 hrs	[99] ○ xx 24 hrs [98] ○ NA
3.k	Normal infant?	[0] ○ 0 No [1] ○ 1 Yes [98] ○ NA
3.l	If No, specify abnormality:	[99] ○ A200 [98] ○ NA
3.m	Contributing factors to abnormality	[99] ○ A200 [98] ○ NA

If more than 3 babies, record physical characteristics and any abnormality and contributing factors in comments.

4.*	14. Comments:	[99] ○ A200 [98] ○ NA

* Item is not required

DVCAT=PROTOCOLVIOLATION
DOMAIN: **DV**

CTN0028 : Protocol Violation Log (PVL) - Repeating Form

#	Node PI	Site Principal Investigator	Site PI of Record	1 Site PV #	2 Date of Violation	3 Part ID #	4 Violation Type	5 Reported by	6 Date Reported	7 Date Site PI of Record notified of PV	8 Date this Log first faxed to Protocol Implementation Director of local regulatory staff	9 QA Monitor (s) reviewing	10 Date(s) of QA	11 Initials of QA monitor indicating that PV has been	Description of violation	Date and Current Status of	PV Resolution
1																	

QNAM=NODEPI
QLABEL=NODE PRINCIPAL INVESTIGATOR
IDVAR=DVSEQ

Adolescent ADHD with SUD and OROS med

1.	Node Principal Investigator	A50
2.	Site Principal Investigator	A50
3.	Site PI of Record	A50

QNAM=SITEPI
QLABEL=SITE PRINCIPAL INVESTIGATOR
IDVAR=DVSEQ

QNAM=STEPIREC
QLABEL=SITE PI OF RECORD
IDVAR=DVSEQ

General Information on protocol violation:

4.	1. SitePV	DVSPID	xxx
5.	2. Violation Date	DVSTDTC	Req / Req
6.	3. Part ID		xxxx
7.	4. Violation Type	DVDECOD	Pulldown List 1 If Other, Specify
8.	5. Reported by		A10
9.	6. Reported Date		Req / Req / Re
10.	7. Date Site		Req / Req / Re
11.	8. Date Log		Req / Req / Req (2005-2009)
12.	9. QA Monitor		A20
13.	10. Date QA		NReq / Req / Req (2005-2009)
14.	11. Initials of QA		A3
15.	Description	DVTERM	A200
16.	Current Status		A200
17.	Resolution		A200

QNAM=PARTID
QLABEL=PART ID
IDVAR=DVSEQ

QNAM=TYPEO
QLABEL=VIOLATION TYPE: OTHER
IDVAR=DVSEQ

QNAM=QAMON
QLABEL=QA MONITOR
IDVAR=DVSEQ

QNAM=REPTBY
QLABEL=REPORTED BY
IDVAR=DVSEQ

QNAM=REPTDATE
QLABEL=REPORTED DATE
IDVAR=DVSEQ

QNAM=SITEDATE
QLABEL=DATE SITE
IDVAR=DVSEQ

QNAM=LOGDATE
QLABEL=DATE LOG
IDVAR=DVSEQ

QNAM=QADATE
QLABEL=DATE OF QA
IDVAR=DVSEQ

QNAM=QAINIT
QLABEL=INITIALS OF QA
IDVAR=DVSEQ

QNAM=CURRSTAT
QLABEL=CURRENT STATUS
IDVAR=DVSEQ

QNAM=RESOLVE
QLABEL=RESOLUTION
IDVAR=DVSEQ

CRB Electronic Signature Affidavit

By my dated signature below, I, [*First Name*] [*Last Name*], verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this patient.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked **Submit** below.

CRF Electronic Signature Affidavit

By my dated signature below, I, [*First Name*] [*Last Name*], verify that this case report form accurately displays the results of the examinations, tests, evaluations and treatments noted within.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked **Submit** below.

DATA NOT ENTERED