

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

43238

Subject ID

990101

site #

-

subject #

Protocol #

NIDA - CPU - ATOXOXITINE - 0001

☐ Not Done

ADVERSE EVENTS (AE)

INSTRUCTIONS: Complete CRF at the follow-up visit, including all adverse events the subject experiences from signing of informed consent to follow-up visit. If the AE is continuing at study follow-up, the stop date may be left blank.

Are any AEs reported on this page? ☐ YES ☐ NO

If yes, please list below using legend:

A. SEVERITY

- 1 = Mild
- 2 = Moderate
- 3 = Severe

B. STUDY DRUG RELATIONSHIP

- 1 = Definitely
- 2 = Probably
- 3 = Possibly
- 4 = Remotely
- 5 = Definitely Not
- 6 = Unknown

C. ACTION TAKEN REGARDING INVESTIGATIONAL AGENT

- 1 = None
- 2 = Discontinued Perm.
- 3 = Discontinued Temp.
- 4 = Reduced Dose
- 5 = Increased Dose
- 6 = Delayed Dose
- 7 = Continued Dose
- 8 = Unknown

D. OUTCOME OF AE

- 1=Recovered/resolved
- 2=Recovering/resolving
- 3=Not recovered/not resolved
- 4=Recovered/resolved with sequelae
- 5=Fatal

Adverse Event

Onset Date (mm/dd/yyyy)

End Date (mm/dd/yyyy)

A. B. C. D. Serious?

/ /

/ /

A. B. C. D.

yes*
no

/ /

/ /

A. B. C. D.

yes*
no

/ /

/ /

A. B. C. D.

yes*
no

/ /

/ /

A. B. C. D.

yes*
no

/ /

/ /

A. B. C. D.

yes*
no

/ /

/ /

A. B. C. D.

yes*
no

*If yes, complete SAE form.

Completed by (initials):

Date completed

/ /

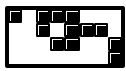
20

mm / dd / yyyy

Page

of





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Subject ID

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NIDA

- CPU

- ATOMOXETINE

- 0001

☐

Not Done

BREATHALYZER ALCOHOL TEST

Study Day: ● Intake Screening

Test Date

/ / 20

mm / dd / yyyy

Alcohol Breathalyzer Result:

0.

mg/mL

Comments:

Completed by (initials):



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NIDA

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- 0001

☐ Not Done

ARCI

INSTRUCTIONS: Fill in study day and complete assessment date in mm/dd/yyyy format.

Inpatient study day:

(i.e -4, 3, 23)

Assessment Date

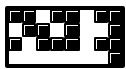
 / / 20

mm / dd / yyyy

- ☐ True ☐ False 1. Speech is slurred
- ☐ True ☐ False 2. Not as active as usual
- ☐ True ☐ False 3. Feeling of dragging
- ☐ True ☐ False 4. Feel sluggish
- ☐ True ☐ False 5. Head feels heavy
- ☐ True ☐ False 6. Feel like avoiding
- ☐ True ☐ False 7. Feel dizzy
- ☐ True ☐ False 8. Harder to move around
- ☐ True ☐ False 9. I am moody
- ☐ True ☐ False 10. I am a little dull
- ☐ True ☐ False 11. I feel drowsy
- ☐ True ☐ False 12. I am full of energy
- ☐ True ☐ False 13. Say things easiest
- ☐ True ☐ False 14. Things more pleasing
- ☐ True ☐ False 15. Pleasant feelings
- ☐ True ☐ False 16. Lose contentment
- ☐ True ☐ False 17. Complete harmony
- ☐ True ☐ False 18. Appreciate saying
- ☐ True ☐ False 19. Happy all the time
- ☐ True ☐ False 20. So good others know
- ☐ True ☐ False 21. Something pleasant
- ☐ True ☐ False 22. Be happy all the time
- ☐ True ☐ False 23. More clear headed
- ☐ True ☐ False 24. More popular

Completed by (initials):

- ☐ True ☐ False 25. Pleasant emptiness
- ☐ True ☐ False 26. Thoughts come easier
- ☐ True ☐ False 27. Less discouraged
- ☐ True ☐ False 28. Mood to talk
- ☐ True ☐ False 29. More excited
- ☐ True ☐ False 30. Answering was easy
- ☐ True ☐ False 31. Memory sharper
- ☐ True ☐ False 32. Could write for hours
- ☐ True ☐ False 33. Very patient
- ☐ True ☐ False 34. Body is tingling
- ☐ True ☐ False 35. Have weird feeling
- ☐ True ☐ False 36. Movements faster
- ☐ True ☐ False 37. Movements slower
- ☐ True ☐ False 38. Better control
- ☐ True ☐ False 39. Mind on task
- ☐ True ☐ False 40. Don't like reading
- ☐ True ☐ False 41. Spending longer
- ☐ True ☐ False 42. Hands feel clumsy
- ☐ True ☐ False 43. Hands shake
- ☐ True ☐ False 44. Disturbed stomach
- ☐ True ☐ False 45. Bodily sensations
- ☐ True ☐ False 46. Anxious and upset
- ☐ True ☐ False 47. Weakness of muscles
- ☐ True ☐ False 48. Thrill through me
- ☐ True ☐ False 49. Movements are free



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- [] [] [] []

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NIDA - CPU - ATOMOXETINE - 0001

☐

Not Done

ADDICTION SEVERITY INDEX(ASI): LITE

Study Day: ● Intake Screening

Assessment Date

[] [] / [] [] / 20 [] []

mm / dd / yyyy

MEDICAL STATUS

1. How many times in your life have you been hospitalized for medical problems?

(Include overdoses and delirium tremens (DTs) but exclude detox.)

2. Do you have any chronic medical problem(s) which continue to interfere with your life?

☐ Yes ☐ No

If yes to #2, specify:

3. Are you taking any prescribed medication on a regular basis for a physical problem?

☐ Yes ☐ No

If yes to #3, specify:

4. Do you receive a pension for a physical disability? (Exclude psychiatric disabilities.)

☐ Yes ☐ No

If yes to #4, specify:

5. How many days have you experienced medical problems in the past 30 days?

FOR QUESTIONS 7 AND 8 PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE.

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

☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

7. How important to you now is treatment for these medical problems?

☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely**CONFIDENCE RATINGS**

Is the above information significantly distorted by:

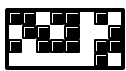
8. Subject's misrepresentation?

☐ Yes ☐ No

9. Subject's inability to understand?

☐ Yes ☐ No

10. Comments:



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ADDICTION SEVERITY INDEX: LITE

1. Education completed (GED = 12 years):

[] []

years

[] []

months

2. Training or technical education completed:

[] []

months

3. Do you have a valid driver's license?

☐ Yes ☐ No

4. Do you have an automobile available?

☐ Yes ☐ No

(Answer "no" if no valid driver's license.)

5. How long was your longest full-time job?

[] []

years

[] []

months

6a. Usual (or last) occupation:

[] [] [] [] [] [] [] [] [] []

6b. Hollingshead occupational category:

1

2

3

4

5

6

7

8

9

☐☐☐☐☐☐☐☐☐

1 = Higher executive, doctoral level professional, owner of large business

2 = Business manager, owner of medium business, other professional

3 = Administrative personnel, manager, owner/proprietor of small business

4 = Clerical and sales, technician

5 = Skilled manual

6 = Semi-skilled

7 = Unskilled

8 = Homemaker

9 = Student, disabled, no occupation

7. Does someone contribute the majority of your support?

☐ Yes ☐ No

8. Usual employment pattern, past 3 years.

☐

1 = full time (35+ hrs/week)

☐

2 = part time (regular hours)

☐

3 = part time (irregular)

☐

4 = student

☐

5 = military service

☐

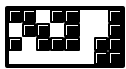
6 = retired/disabled

☐

7 = unemployed

☐

8 = in controlled environment



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ADDICTION SEVERITY INDEX: LITE

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

How much money did you receive from the following sources in the past 30 days?

10. Employment (net income)

\$

11. Unemployment compensation

\$

12. Public assistance (welfare)

\$

13. Pension, benefits or social security

\$

14. Mate, family or friends (money for personal expenses)

\$

15. Illegal

\$

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

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

FOR QUESTIONS 18 AND 19 PLEASE ASK SUBJECT TO USE THE SUBJECT RATING SCALE.

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

☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

19. How important to you now is counseling for these employment problems?

☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

CONFIDENCE RATINGS

Is the above information significantly distorted by:

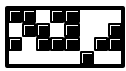
20. Subject's misrepresentation?

☐ Yes ☐ No

21. Subject's inability to understand?

☐ Yes ☐ No

22. Comments:



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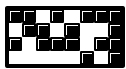
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ADDICTION SEVERITY INDEX: LITE



	Days in Past 30 Days	Lifetime (Years)	Route of Administration				
			oral	nasal	smoking	non-iv inj.	iv inj.
1. Alcohol - any use at all	 	 	<input type="radio"/>				
2. Alcohol - to intoxication	 	 	<input type="radio"/>				
3. Heroin	 	 	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Methadone	 	 	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Other opiates/analgesics	 	 	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Barbiturates	 	 	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Sedatives/hypnotics/tranquilizers	 	 	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Cocaine	 	 	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. Amphetamines	 	 	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Cannabis	 	 	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
11. Hallucinogens	 	 	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Inhalants	 	 	<input type="radio"/>	<input type="radio"/>			
13. More than one substance per day (including alcohol)	 	 					



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14. How many times have you had alcohol DTs?

How many times in your life have you been treated for:

15. Alcohol abuse

16. Drug abuse

How many of these were detox only?

17. Alcohol

18. Drug

How much money have you spent during the past 30 days on:

19. Alcohol

\$

20. Drugs

\$

21. How many days have you been treated in an outpatient setting for alcohol or drugs in the past 30 days? (Include NA, AA.)

How many days in the past 30 days have you experienced:

22. Alcohol problems

23. Drug problems

FOR QUESTIONS 24 - 27 PLEASE ASK SUBJECT TO USE THE SUBJECT RATING SCALE.

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

24. Alcohol problems

☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

25. Drug problems

☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

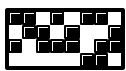
How important to you now is treatment for these:

26. Alcohol problems

☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

27. Drug problems

☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely



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ADDICTION SEVERITY INDEX: LITE

CONFIDENCE RATINGS

Is the above information significantly distorted by:

28. Subject's misrepresentation?

☐ Yes ☐ No

29. Subject's inability to understand?

☐ Yes ☐ No

30. Comments:

1. Was this admission prompted or suggested by the criminal justice system (judge, probation/parole officer, etc.)? ☐ Yes ☐ No

2. Are you on probation or parole? ☐ Yes ☐ No

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

3. Shoplifting/vandalism

4. Parole/probation violation(s)

5. Drug charge(s)

6. Forgery

7. Weapons offense

8. Burglary, larceny, breaking and entering

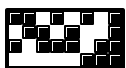
9. Robbery

10. Assault

11. Arson

12. Rape

13. Homicide, manslaughter



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ADDICTION SEVERITY INDEX: LITE

14. Prostitution

15. Contempt of court

16. Other, specify:

17. How many of these charges resulted in conviction?

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

18. Disorderly conduct, vagrancy, public intoxication?

19. Driving while intoxicated?

20. Major driving violations (reckless driving, speeding, no license, etc.)?

21. How many months were you incarcerated in your life?

months

22. Are you presently awaiting charges, trial or sentence?

☐ Yes ☐ No

23. What for?

(if multiple charges use most severe from codes for 3 through 16 above)

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

days

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

days

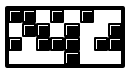
FOR QUESTIONS 26 - 27 PLEASE ASK SUBJECT TO USE THE SUBJECT RATING SCALE.

26. How serious do you feel your present legal problems are?

☐ 0 = None at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

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

☐ 0 = None at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely



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9	9	0	1	0	1
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C	P	U
---	---	---

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A	T	O	M	O	X	E	T	I	N	E
---	---	---	---	---	---	---	---	---	---	---

 -

0	0	0	1
---	---	---	---

site # subject #

ADDICTION SEVERITY INDEX: LITE

CONFIDENCE RATINGS

Is the above information significantly distorted by:

28. Subject's misrepresentation? ☐ Yes ☐ No

29. Subject's inability to understand? ☐ Yes ☐ No

30. Comments:

--

FAMILY/SOCIAL RELATIONSHIPS

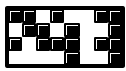
1. Marital status:

- ☐ 1= married
- ☐ 2= remarried
- ☐ 3= widowed
- ☐ 4= separated
- ☐ 5= divorced
- ☐ 6= never married

2. Are you satisfied with this situation? ☐ Yes ☐ No ☐ Indifferent

3. Usual living arrangements (past three years):

- ☐ 1 = with sexual partner and children
- ☐ 2 = with sexual partner alone
- ☐ 3 = with children alone
- ☐ 4 = with parents
- ☐ 5 = with family
- ☐ 6 = with friends
- ☐ 7 = alone
- ☐ 8 = controlled environment
- ☐ 9 = no stable arrangements



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4. Are you satisfied with these living arrangements?

☐ Yes ☐ No ☐ Indifferent**Do you live with anyone who:**

5. Has a current alcohol problem?

☐ Yes ☐ No

6. Uses non-prescribed drugs?

☐ Yes ☐ No

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

☐ Family ☐ Friends ☐ Alone

8. Are you satisfied with spending your free time this way?

☐ Yes ☐ No ☐ Indifferent**Have you had any significant periods in which you have experienced serious problems getting along with:****In the past 30 days****Lifetime**

	Yes	No	I don't know	Not applicable		Yes	No	I don't know	Not applicable
9. Mother	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Father	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Siblings	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. Sexual partner/spouse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. Children	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. Other significant family	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

15. If 14 is yes, specify:

16. Close Friends

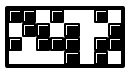
☐ ☐ ☐ ☐☐ ☐ ☐ ☐

17. Neighbors

☐ ☐ ☐ ☐☐ ☐ ☐ ☐

18. Co-workers

☐ ☐ ☐ ☐☐ ☐ ☐ ☐



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ADDICTION SEVERITY INDEX: LITE**Did any of these people (#'s 9 - 18 above) abuse you?****In the past 30 days****Lifetime**

19. Physically (caused you physical harm) ☐ Yes ☐ No ☐ Yes ☐ No
20. Sexually (forced sexual advances or sexual acts) ☐ Yes ☐ No ☐ Yes ☐ No

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

21. With your family:

22. With other people excluding family:

FOR QUESTIONS 23 - 26 PLEASE ASK SUBJECT TO USE THE SUBJECT RATING SCALE.

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

23. Family problems

- ☐
- 0 = Not at all
- ☐
- 1 = Slightly
- ☐
- 2 = Moderately
- ☐
- 3 = Considerably
- ☐
- 4 = Extremely

24. Social problems

- ☐
- 0 = Not at all
- ☐
- 1 = Slightly
- ☐
- 2 = Moderately
- ☐
- 3 = Considerably
- ☐
- 4 = Extremely

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

25. Family problems

- ☐
- 0 = Not at all
- ☐
- 1 = Slightly
- ☐
- 2 = Moderately
- ☐
- 3 = Considerably
- ☐
- 4 = Extremely

26. Social problems

- ☐
- 0 = Not at all
- ☐
- 1 = Slightly
- ☐
- 2 = Moderately
- ☐
- 3 = Considerably
- ☐
- 4 = Extremely

CONFIDENCE RATINGS

Is the above information significantly distorted by:

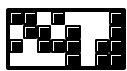
27. Subject's misrepresentation?

- ☐
- Yes
- ☐
- No

28. Subject's inability to understand?

- ☐
- Yes
- ☐
- No

29. Comments:



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ADDICTION SEVERITY INDEX: LITE

PSYCHIATRIC STATUS

How many times have you been treated for any psychological or emotional problem(s)?

1. In a hospital

2. As an outpatient or private patient

3. Do you receive a pension for a psychiatric disability? ☐ Yes ☐ No

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

In the past 30 days

Lifetime

4. Experienced serious depression?

☐ Yes ☐ No

☐ Yes ☐ No

5. Experienced serious anxiety or tension?

☐ Yes ☐ No

☐ Yes ☐ No

6. Experienced hallucinations?

☐ Yes ☐ No

☐ Yes ☐ No

7. Experienced trouble understanding, concentrating, or remembering?

☐ Yes ☐ No

☐ Yes ☐ No

8. Experienced trouble controlling violent behavior?

☐ Yes ☐ No

☐ Yes ☐ No

9. Experienced serious thoughts of suicide?

☐ Yes ☐ No

☐ Yes ☐ No

10. Attempted suicide?

☐ Yes ☐ No

☐ Yes ☐ No

11. Been prescribed medication for any psychological or emotional problem?

☐ Yes ☐ No

☐ Yes ☐ No

12. How many days in the last 30 have you experienced psychological or emotional problems?

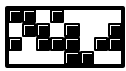
FOR QUESTIONS 13 - 14 PLEASE ASK SUBJECT TO USE THE SUBJECT RATING SCALE.

13. How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days?

☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

14. How important to you now is treatment for these psychological problems?

☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely



27067

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

9	9	0	1	0	1
---	---	---	---	---	---

 -

--	--	--	--

 Protocol #

N	I	D	A
---	---	---	---

 -

C	P	U
---	---	---

 -

A	T	O	M	O	X	E	T	I	N	E
---	---	---	---	---	---	---	---	---	---	---

 -

0	0	0	1
---	---	---	---

site # subject #

ADDICTION SEVERITY INDEX: LITE

CONFIDENCE RATINGS

Is the above information significantly distorted by:

15. Subject's misrepresentation? ☐ Yes ☐ No

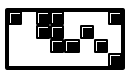
16. Subject's inability to understand? ☐ Yes ☐ No

17. Comments:

--

Completed by (initials):

--	--	--



13338

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID - Protocol # - - -
site # subject #

☐ Not Done

ATOMOXETINE PK

Study Day: ☒ 6
☐ 8 (Session 6)
☐ 11
☐ 13 (Session 8)

Lab Date / /
mm / dd / yyyy

Time Relative to
Study Drug Dose

Atomoxetine
Draw Time
(00:00-23:59)

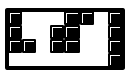
-5 min

:

170 min

:

Completed by (initials):



39385

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA

- CPU

- ATOMOXETINE

- 0001

☐ Not Done

BRIEF PSYCHIATRIC RATING SCALE (BPRS)

INSTRUCTIONS: Fill in study day and complete assessment date in mm/dd/yyyy format.

Inpatient study day:

(i.e -4, 3, 23)

Assessment Date

 / /

mm / dd / yyyy

Instructions: Transcribe from BPRS source document the number selected. Mark 0 for symptoms not assessed.

1. Somatic Concern

2. Anxiety

3. Depression

4. Suicidality

5. Guilt

6. Hostility

7. Elevated Mood

8. Grandiosity

9. Suspiciousness

10. Hallucinations

11. Unusual Thought Content

12. Bizarre Behavior

13. Self-neglect

14. Disorientation

15. Conceptual Disorganization

16. Blunted Affect

17. Emotional Withdrawal

18. Motor Retardation

19. Tension

20. Uncooperativeness

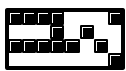
21. Excitement

22. Distractibility

23. Motor Hyperactivity

24. Mannerisms and Posturing

Completed by (initials):



5370

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID - Protocol # - - -
site # subject #

☐ Not Done

BRIEF PSYCHIATRIC RATING SCALE (BPRS)

Study Day: ● -6

☐ Saline☐ 1 (20 mg)☒ 2 (40 mg)

Time Performed

 : (00:00-23:59)

(within 60 min. post infusion)

Instructions: Transcribe from BPRS source document the number selected. Mark 0 for symptoms not assessed.

1. Somatic Concern

2. Anxiety

3. Depression

4. Suicidality

5. Guilt

6. Hostility

7. Elevated Mood

8. Grandiosity

9. Suspiciousness

10. Hallucinations

11. Unusual Thought Content

12. Bizarre Behavior

13. Self-neglect

14. Disorientation

15. Conceptual Disorganization

16. Blunted Affect

17. Emotional Withdrawal

18. Motor Retardation

19. Tension

20. Uncooperativeness

21. Excitement

22. Distractibility

24. Mannerisms and Posturing

Completed by (initials):



27308

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

- [] [] [] []

subject #

Protocol #

NIDA

- CPU

- ATOMOXETINE

- 0001

☐ Not Done

BRIEF PSYCHIATRIC RATING SCALE (BPRS)

☐ -2 (Session 3)☐ 8 (Session 6)Study Day: ☐ -1 (Session 4)☐ 12 (Session 7)☐ 7 (Session 5)☐ 13 (Session 8)☐ 1st Infusion☐ 2nd Infusion

Time Performed

[] [] : [] []

(00:00-23:59)

(within 60 min. post infusion)

Instructions: Transcribe from BPRS source document the number selected. Mark 0 for symptoms not assessed.

1. Somatic Concern

2. Anxiety

3. Depression

4. Suicidality

5. Guilt

6. Hostility

7. Elevated Mood

8. Grandiosity

9. Suspiciousness

10. Hallucinations

11. Unusual Thought Content

12. Bizarre Behavior

13. Self-neglect

14. Disorientation

15. Conceptual Disorganization

16. Blunted Affect

17. Emotional Withdrawal

18. Motor Retardation

19. Tension

20. Uncooperativeness

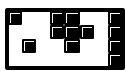
21. Excitement

22. Distractibility

23. Motor Hyperactivity

24. Mannerisms and Posturing

Completed by (initials):



7497

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA - CPU - ATOMOXETINE - 0001

☐

Not Done

BRIEF SUBSTANCE CRAVING SCALE (BSCS) - Inpatient

INSTRUCTIONS: Fill in inpatient study day and complete assessment date in mm/dd/yyyy format. Transcribe responses from the BSCS source document. BSCS should be completed every other day following intake.

Inpatient study day:

(i.e -4, 3, 23)

Assessment Date

 / / 20

mm / dd / yyyy

1. Cocaine Intensity

2. Cocaine frequency

3. Cocaine length

4. Number

5. Hours Craved

Minutes Craved

6. Worst Day Craving

☐ Sunday☐ Monday☐ Tuesday☐ Wednesday☐ Thursday☐ Friday☐ Saturday☐ All days were the same

7. Date Worst Craving

 / / 20

8. Intensity Worst Day

9. Second drug craved

If other circled, specify

10. Second drug intensity

11. Second drug frequency

12. Second drug length

13. Third drug craved

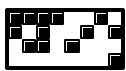
If other circled, specify

14. Third drug intensity

15. Third drug frequency

16. Third drug length

Completed by (initials):



42344

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA

- CPU

- ATOMOXETINE

- 0001

☐ Not Done

BRIEF SUBSTANCE CRAVING SCALE (BSCS)

INSTRUCTIONS: Bubble in study day and complete assessment date in mm/dd/yyyy format. Transcribe responses from the BSCS source document.

Study day: ☒ Intake Screening

Assessment Date

/ / 20

mm / dd / yyyy

1. Cocaine Intensity

2. Cocaine frequency

3. Cocaine length

4. Number

5. Hours Craved

Minutes Craved

6. Worst Day Craving

☐ Sunday☐ Monday☐ Tuesday☐ Wednesday☐ Thursday☐ Friday☐ Saturday☐ All days were the same

7. Date Worst Craving

/ / 20

8. Intensity Worst Day

9. Second drug craved

If other circled, specify

10. Second drug intensity

11. Second drug frequency

12. Second drug length

13. Third drug craved

If other circled, specify

14. Third drug intensity

15. Third drug frequency

16. Third drug length

Completed by (initials):

National Institute on Drug Abuse
Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA-CPU-ATOMOXETINE-0001

☐ Not Done**CHILD BEARING POTENTIAL**

Study Day: ● Pre-Intake Screening

Assessment Date

/ / 20

mm / dd / yyyy

INSTRUCTIONS: Complete this CRF for female participants only.

Is the female subject post menopausal, had a
hysterectomy, or been surgically sterilized?
(if yes, skip down to completed by)

☐ yes ☐ no

If no, is the subject using an acceptable method
of birth control?

☐ yes ☐ no (if no, subject is not eligible to
participate in study)

If yes, what method of birth control?

☐ barrier (diaphragm or condom)
☐ complete abstinence from sexual intercourse

Was a serum pregnancy test performed?

☐ yes ☐ no

Serum Pregnancy Test Date

/ /

mm / dd / yyyy

Pregnancy test result:

☐ Positive
☐ Negative
☐ Unknown

Pregnancy test comments:

Is the subject lactating?

☐ yes ☐ no

Completed by (initials):



7754

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID - Protocol #

site # subject #

☐ Not Done

CHEMISTRIES

Study Day: ☐ Pre-Intake Screening☐ 17 (Discharge)☐ Intake Screening☐ 31 (Follow-up)

Test Date

 / /

mm / dd / yyyy

☐ 6☐ Unscheduled☐ 13 (Session 8)

INSTRUCTIONS: Lab data can be transcribed either by using standard quantity and unit listed at left, **OR** by using other quantity and other unit (specify) text box at right. **You do not need to list lab data twice.**

NORMAL: within lab normal limits, **ABNORMAL:** outside of normal limits but not clinically significant,

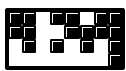
ABNORMAL SIGNIFICANT: significant during screening means subject is ineligible for study; significant while on study means it should be reported as an adverse event.

Analyte	Std. Quantity	Unit	or	Other Quantity	Other Unit (specify)	normal	abnormal	abnormal significant	Not done
Sodium (NA)	<input type="text"/> <input type="text"/> <input type="text"/>	mEq/L*		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Potassium (K)	<input type="text"/> <input type="text"/> <input type="text"/>	mEq/L*		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Chloride (Cl)	<input type="text"/> <input type="text"/> <input type="text"/>	mEq/L*		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
(CO ₂)	<input type="text"/> <input type="text"/> <input type="text"/>	mEq/L*		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Glucose	<input type="text"/> <input type="text"/> <input type="text"/>	mg/dL		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Creatinine	<input type="text"/> <input type="text"/> <input type="text"/>	mg/dL		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
SGOT/AST	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	U/L		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
SGPT/ALT	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	U/L		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
GGT	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	U/L		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Total Bilirubin	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	mg/dL		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
LDH	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	U/L		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
CPK	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	U/L		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Alkaline phosphatase	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	U/L		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
BUN	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	mg/dL		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Provide comments for any abnormal value(s):

Completed by (initials):

* mEq/L = mmol/L



53077

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA

- CPU

- ATOMOXETINE

- 0001

☐

Not Done

COCAINE PK

☐ -1 (Session 4)Study Day: ☐ 8 (Session 6)☐ 13 (Session 8)

Time Relative
to 1st
Infusion

Cocaine PK
Draw Time
(00:00-23:59)

-20 min

 :

+3 min

 :

10 min

 :

20 min

 :

30 min

 :

58 min

 :

63 min

 :

70 min

 :

80 min

 :

90 min

 :

105 min

 :

120 min

 :

180 min

 :

300 min

 :

420 min

 :

Completed by (initials):

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA - CPU - ATOMOXETINE - 0001

10072

☐ Not Done

CONCOMITANT MEDICATIONS

INSTRUCTIONS: Complete CRF at follow-up visit, transferring all medications listed on the ConMed Log.

Are any Con Meds reported on this page? ☐ YES ☐ NO

If yes, list below using the provided legend:

DOSE	UNIT OF MEDICATION	FREQUENCY	ROUTE OF ADMINISTRATION
Number (e.g. 0.4, 1, 81) UNK = unknown	CAP = capsule g = gram GR = grain GTT = drop ug = microgram uL = microliter mg = milligram mL = milliliter OZ = ounce PUF = puff SPY = spray/squirt SUP = suppository TSP = teaspoon TBS = tablespoon TAB = tablet UNK = unknown OTH = other	ONCE = one time only QD = once daily BID = twice daily TID = three times a day QID = four times a day QOD = every other day PRN = as needed UNK = unknown OTH = other	PO = oral TD = transdermal INH = inhaled IM = intramuscular IV = intravenous REC = rectal VAG = vaginal SQ = subcutaneous SL = sublingual AUR = auricular IA = intra-articular IO = intraocular UNK = unknown OTH = other

Medication Name	Reason	Dose	Unit	Freq.	Route	Start Date (mm/dd/yyyy)	Stop Date (mm/dd/yyyy)

Completed by (initials):

Date completed:

/

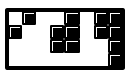
/

20

mm / dd / yyyy

Page

of



39705

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA - CPU - ATOMOXETINE - 0001

DEATH REPORT

INSTRUCTIONS: Complete and fax to TRI within 24 hours of event occurring.

Subject date of death

/ /

mm / dd / yyyy

Was autopsy performed?

☐

yes

☐

no

☐

unknown

If yes, is autopsy report available?

☐

yes*

☐

no

Is cause of death known?

☐

yes

☐

no

If yes, in the investigator's clinical judgment, what was the primary cause of death?

Narrative description of death (include information about why cause of death is unknown, if applicable.)

* Insert a copy of the autopsy report in source document binder behind Death Report.

Completed by (initials):

Date completed

/ /

mm / dd / yyyy



13011

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

- [] [] [] []

subject #

Protocol #

NIDA - CPU - ATOMOXETINE - 0001

☐ Not Done

DEMOGRAPHICS

Study Day: ☒ Pre-Intake Screening

Assessment Date

[] [] / [] [] / 20 [] []

mm / dd / yyyy

1. Gender: ☐ Male ☐ Female

2. Date of Birth

[] [] / [] [] / [] [] [] [] mm / dd / yyyy

3. Do you identify yourself as Spanish, Hispanic, or Latino?

☐ No (If no, skip to question 4)☐ Yes, I see myself as (mark any that apply):☐ Mexican, Mexican American or Chicano☐ Puerto Rican☐ Cuban☐ Other Spanish, Hispanic or Latino (specify)

4. Ethnicity/Race :

For each of the following, answer Yes to all that apply and No to those that do not. If you mark Yes, specify subgroup by marking all that apply.

☐ Yes ☐ No American Indian or Alaskan Native☐ Yes ☐ No Asian (mark all that apply)☐ Asian Indian☐ Chinese☐ Filipino☐ Japanese☐ Korean☐ Vietnamese☐ Other (specify)☐ Yes ☐ No Black or African American☐ Yes ☐ No Native Hawaiian or Pacific Islander (mark all that apply)☐ Native Hawaiian☐ Guamanian or Chamorro☐ Samoan☐ Other (specify)☐ Yes ☐ No White☐ Yes ☐ No Other (specify)☐ Participant chooses not to answer☐ Unknown

Completed by (initials):

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - Protocol # NIDA - CPU - ATOMOXETINE - 0001

site # subject #

☐ Not Done **12 LEAD ELECTROCARDIOGRAM (ECG) - INFUSION**

Study Day: ☐ -6 (Session 1 & 2)

Schd Time: ☐ -70 min pre ☐ 40 min post
☐ -56 min pre ☐ 64 min post
☐ -20 min pre ☐ 100 min post
☐ 4 min post

Actual Time

 :

(00:00-23:59)

A. ECG overall results were: ☐ Normal ☐ Abnormal

If ECG was normal, skip to question C; otherwise indicate if any result was **ABNORMAL** but does not exclude the subject from participation in the study, or **ABNORMAL SIGNIFICANT** and does preclude (continued) participation in the study.

B. Abnormal results were:

	abnormal	abnormal significant		abnormal	abnormal significant
1. Increased QRS Voltage	<input type="radio"/>	<input type="radio"/>	17. Supraventricular Premature Beat	<input type="radio"/>	<input type="radio"/>
2. QTc Prolongation	<input type="radio"/>	<input type="radio"/>	18. Ventricular Premature Beat	<input type="radio"/>	<input type="radio"/>
3. Left Atrial Hypertrophy	<input type="radio"/>	<input type="radio"/>	19. Supraventricular Tachycardia	<input type="radio"/>	<input type="radio"/>
4. Right Atrial Hypertrophy	<input type="radio"/>	<input type="radio"/>	20. Ventricular Tachycardia	<input type="radio"/>	<input type="radio"/>
5. Left Ventricular Hypertrophy	<input type="radio"/>	<input type="radio"/>	21. Atrial Fibrillation	<input type="radio"/>	<input type="radio"/>
6. Right Ventricular Hypertrophy	<input type="radio"/>	<input type="radio"/>	22. Atrial Flutter	<input type="radio"/>	<input type="radio"/>
7. Acute Infarction	<input type="radio"/>	<input type="radio"/>	23. Other Rhythm Abnormalities	<input type="radio"/>	<input type="radio"/>
8. Subacute Infarction	<input type="radio"/>	<input type="radio"/>	24. Implanted Pacemaker	<input type="radio"/>	<input type="radio"/>
9. Old Infarction	<input type="radio"/>	<input type="radio"/>	25. 1st Degree A-V Block	<input type="radio"/>	<input type="radio"/>
10. Myocardial Ischemia	<input type="radio"/>	<input type="radio"/>	26. 2nd Degree A-V Block	<input type="radio"/>	<input type="radio"/>
11. Digitalis Effect	<input type="radio"/>	<input type="radio"/>	27. 3rd Degree A-V Block	<input type="radio"/>	<input type="radio"/>
12. Symmetrical T-Wave Inversions	<input type="radio"/>	<input type="radio"/>	28. LBB Block	<input type="radio"/>	<input type="radio"/>
13. Poor R-Wave Progression	<input type="radio"/>	<input type="radio"/>	29. RBB Block	<input type="radio"/>	<input type="radio"/>
14. Other Nonspecific ST/T	<input type="radio"/>	<input type="radio"/>	30. Pre-excitation Syndrome	<input type="radio"/>	<input type="radio"/>
15. Sinus Tachycardia	<input type="radio"/>	<input type="radio"/>	31. Other Intraventricular Condition Block	<input type="radio"/>	<input type="radio"/>
16. Sinus Bradycardia	<input type="radio"/>	<input type="radio"/>	32. Other, specify:	<input type="radio"/>	<input type="radio"/>

C. Ventricular rate (bpm):

E. QRS (ms):

D. PR (ms):

F. RR (ms):

G. QT (ms):

Completed by (initials):

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

- [] [] [] []

subject #

Protocol #

NIDA-CPU-ATOMOXETINE-0001

☐ Not Done 12 LEAD ELECTROCARDIOGRAM (ECG) - INFUSION

Study Day: ☐ -2 (Session 3) ☐ 8 (Session 6)
☐ -1 (Session 4) ☐ 12 (Session 7)
☐ 7 (Session 5) ☐ 13 (Session 8)

☐ -10 min pre ☐ 64 min post
 Schd Time: ☐ 4 min post ☐ 100 min post
☐ 40 min post

Actual Time [] [] : [] [] (00:00-23:59)

A. ECG overall results were: ☐ Normal ☐ Abnormal

If ECG was normal, skip to question C; otherwise indicate if any result was **ABNORMAL** but does not exclude the subject from participation in the study, or **ABNORMAL SIGNIFICANT** and does preclude (continued) participation in the study.

B. Abnormal results were:

	abnormal	abnormal significant		abnormal	abnormal significant
1. Increased QRS Voltage	<input type="radio"/>	<input type="radio"/>	17. Supraventricular Premature Beat	<input type="radio"/>	<input type="radio"/>
2. QTc Prolongation	<input type="radio"/>	<input type="radio"/>	18. Ventricular Premature Beat	<input type="radio"/>	<input type="radio"/>
3. Left Atrial Hypertrophy	<input type="radio"/>	<input type="radio"/>	19. Supraventricular Tachycardia	<input type="radio"/>	<input type="radio"/>
4. Right Atrial Hypertrophy	<input type="radio"/>	<input type="radio"/>	20. Ventricular Tachycardia	<input type="radio"/>	<input type="radio"/>
5. Left Ventricular Hypertrophy	<input type="radio"/>	<input type="radio"/>	21. Atrial Fibrillation	<input type="radio"/>	<input type="radio"/>
6. Right Ventricular Hypertrophy	<input type="radio"/>	<input type="radio"/>	22. Atrial Flutter	<input type="radio"/>	<input type="radio"/>
7. Acute Infarction	<input type="radio"/>	<input type="radio"/>	23. Other Rhythm Abnormalities	<input type="radio"/>	<input type="radio"/>
8. Subacute Infarction	<input type="radio"/>	<input type="radio"/>	24. Implanted Pacemaker	<input type="radio"/>	<input type="radio"/>
9. Old Infarction	<input type="radio"/>	<input type="radio"/>	25. 1st Degree A-V Block	<input type="radio"/>	<input type="radio"/>
10. Myocardial Ischemia	<input type="radio"/>	<input type="radio"/>	26. 2nd Degree A-V Block	<input type="radio"/>	<input type="radio"/>
11. Digitalis Effect	<input type="radio"/>	<input type="radio"/>	27. 3rd Degree A-V Block	<input type="radio"/>	<input type="radio"/>
12. Symmetrical T-Wave Inversions	<input type="radio"/>	<input type="radio"/>	28. LBB Block	<input type="radio"/>	<input type="radio"/>
13. Poor R-Wave Progression	<input type="radio"/>	<input type="radio"/>	29. RBB Block	<input type="radio"/>	<input type="radio"/>
14. Other Nonspecific ST/T	<input type="radio"/>	<input type="radio"/>	30. Pre-excitation Syndrome	<input type="radio"/>	<input type="radio"/>
15. Sinus Tachycardia	<input type="radio"/>	<input type="radio"/>	31. Other Intraventricular Condition Block	<input type="radio"/>	<input type="radio"/>
16. Sinus Bradycardia	<input type="radio"/>	<input type="radio"/>	32. Other, specify:	<input type="radio"/>	<input type="radio"/>

C. Ventricular rate (bpm): [] [] []

E. QRS (ms): [] [] []

D. PR (ms): [] [] []

F. RR (ms): [] [] [] []

G. QT (ms): [] [] []

Completed by (initials): [] [] []



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National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

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site #

subject #

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NIDA

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ATOMOXETINE

0001

☐ Not Done

12 LEAD ELECTROCARDIOGRAM (ECG)

Study Day: ☐ Pre-Intake Screening☐ Intake Screening☐ 17 (Discharge)☐ 31 (Follow-up)☐ Unscheduled

Test Date

/ / 20

mm / dd / yyyy

Time

: (00:00-23:59)

A. ECG overall results were:

☐ Normal ☐ Abnormal

If ECG was normal, skip to question C; otherwise indicate if any result was **ABNORMAL** but does not exclude the subject from participation in the study, or **ABNORMAL SIGNIFICANT** and does preclude (continued) participation in the study.

B. Abnormal results were:

1. Increased QRS Voltage

abnormal

abnormal significant

2. QTc Prolongation

3. Left Atrial Hypertrophy

4. Right Atrial Hypertrophy

5. Left Ventricular Hypertrophy

6. Right Ventricular Hypertrophy

7. Acute Infarction

8. Subacute Infarction

9. Old Infarction

10. Myocardial Ischemia

11. Digitalis Effect

12. Symmetrical T-Wave Inversions

13. Poor R-Wave Progression

14. Other Nonspecific ST/T

15. Sinus Tachycardia

16. Sinus Bradycardia

17. Supraventricular Premature Beat

18. Ventricular Premature Beat

19. Supraventricular Tachycardia

20. Ventricular Tachycardia

21. Atrial Fibrillation

22. Atrial Flutter

23. Other Rhythm Abnormalities

24. Implanted Pacemaker

25. 1st Degree A-V Block

26. 2nd Degree A-V Block

27. 3rd Degree A-V Block

28. LBB Block

29. RBB Block

30. Pre-excitation Syndrome

31. Other Intraventricular Condition Block

32. Other, specify:

abnormal

abnormal significant

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

C. Ventricular rate (bpm):

/ /

E. QRS (ms):

/ /

D. PR (ms):

/ /

F. RR (ms):

/ / /

G. QT (ms):

/ /

Completed by (initials):

/ /



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National Institute on Drug Abuse**Atomoxetine-Cocaine Interaction Study**

Subject ID

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- [] [] [] []

subject #

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END OF TRIAL

INSTRUCTIONS: Complete and fax to TRI within 24 hours of event occurring.

1. End of Trial date

(last inpatient day or day of early termination)

[] []

/ [] []

20 [] []

mm / dd / yyyy

2. Hospital Discharge Date

[] []

/ [] []

20 [] []

mm / dd / yyyy

3 Status at end of Trial (Select one)

☐ Subject completed study☐ Subject was a screen failure (not enrolled - complete question 6 below)☐ Subject did not complete the study (early withdrawal - complete question 7 below)

4 Did the subject receive all protocol defined study treatments?

☐ Yes☐ NoLast date of study drug
treatment

[] []

/ [] []

20 [] []

mm / dd / yyyy

5 Did the subject complete follow-up as prescribed in the protocol?

☐ Yes☐ NoFollow-up completion
date

[] []

/ [] []

20 [] []

mm / dd / yyyy

6 If subject was a screening failure, indicate the primary reason for screening failure

☐ Did not complete screening process☐ Did not meet study eligibility criteria

7 If subject did not complete the study, indicate the primary reason for withdrawal

☐ Subject was determined after enrollment to be ineligible☐ Subject requested to withdraw (Provide comments)☐ Subject experienced adverse event prompting early termination by PI☐ Subject terminated for administrative reasons (protocol non-compliance - provide comments)☐ Subject transferred to another treatment program (complete question 7 below)☐ Subject was incarcerated☐ Subject became pregnant☐ Subject developed sensitivity to study agent☐ Subject was lost to follow-up☐ Subject moved from area☐ Subject dies (Complete Death Report CRF)☐ Subject can no longer attend clinic☐ Subject no longer attends clinic☐ Subject is in a controlled environment☐ Other (provide comments)

8 If subject transferred to another treatment program, select treatment program type

☐ Methadone☐ LAAM☐ Drug Free☐ Inpatient Detox or Treatment☐ Therapeutic Community☐ Other, specify

If requested, provide additional comments:

Completed by (initials):

[] []

Date form completed

[] []

/ [] []

20 [] []

mm / dd / yyyy



11460

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID - Protocol # - - -
site # subject #

ENROLLMENT

INSTRUCTIONS: Complete and fax to TRI within 24 hours of event occurring.

Is subject eligible for participation based on the Eligibility Criteria?(required field) ☐ yes ☐ no*
*if no, skip to completed by field and complete End of Trial CRF marking Screen Failure

If yes, was subject enrolled into the study? ☐ yes ☐ no

If yes, date enrolled: / / mm / dd / yyyy

If no,(subject was eligible but not enrolled), indicate reason:
(Complete End of Trial CRF marking Other and specify in text box exact reason)

- ☐ failed to return to clinic
☐ declined study participation
☐ other, specify:

Completed by (initials):

Date completed / /
mm / dd / yyyy



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National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

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Protocol #

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☐

Not Done

HIV TEST

Study Day: ● Intake Screening

Test Date

/ / 20

mm / dd / yyyy

HIV test type:

- ☐ ELISA
☐ Western Blot
☐ PCR
☐ other (specify)
☐ unknown

HIV test result:

- ☐ positive
☐ negative
☐ unknown

If HIV result is positive,
was confirmatory test
performed?

- ☐ yes
☐ no
☐ unknown

If confirmatory test was done:

Date blood was drawn

/ /

mm / dd / yyyy

Confirmatory test type:

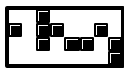
- ☐ ELISA
☐ Western Blot
☐ PCR
☐ other (specify)
☐ unknown

Confirmatory test result:

- ☐ positive
☐ negative
☐ unknown

Comments:

Completed by (initials):



45613

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

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-

subject #

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NIDA - CPU - ATOMOXETINE - 0001

☐ Not Done

INFECTIOUS DISEASE PANEL

Study Day: ● Pre-Intake Screening

Test Date

/ / 20

mm / dd / yyyy

Indicate whether the laboratory value is **NEGATIVE**: negative test result, **POSITIVE**: but **DOES NOT EXCLUDE** subject from participation or continued study participation, **POSITIVE SIGNIFICANT**: significant during screening means subject is ineligible for study; significant while on study means it should be reported as an adverse event, **INDETERMINANT**: result was not interpretable.

	negative	positive	positive significant	indeterminant	not done	Provide comments for any abnormal value.
Hepatitis B surface antigen result	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hepatitis B surface antibody result	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hepatitis B core antibody result	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hepatitis C virus antibody result	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Completed by (initials):

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

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☐ Not Done

INCLUSION/EXCLUSION CRITERIA

INSTRUCTIONS: Mark response in each box, then sign and date source document.

Assessment Date

[] [] / [] [] / 20 [] []

Inclusion Criteria: All responses must be YES for participant to be eligible. The participant must:

1. Meet DSM-IV criteria for cocaine abuse or dependence and is not seeking treatment at time of study. ☐ yes ☐ no
2. Be between 18 - 45 years of age. ☐ yes ☐ no
3. Be within 20% of ideal body weight according to Metropolitan Height and Weight Standards, **and** weigh at least 45kg (99 lbs). ☐ yes ☐ no
4. Be able to verbalize understanding of the consent form, provide written informed consent, and verbalize willingness to complete study procedures. ☐ yes ☐ no
5. Have currently used cocaine by the smoke or intravenous route, and this use must be confirmed by a positive BE urine test once within 30 days prior to entering the study. ☐ yes ☐ no
6. Have a history and brief physical exam that demonstrates no clinically significant contraindication for participating in this study, in the judgment of the admitting physician and site investigator. ☐ yes ☐ no
7. Be male or if female, have a negative pregnancy test within 72 hours prior to receiving the first screening infusion. If patient is not postmenopausal, has had a hysterectomy or has not been sterilized, must agree to follow a birth control method specified in protocol ☐ yes ☐ no
8. Be able to comply with protocol requirement, Clinical Pharmacology Unit (CPU) rules and regulation and be likely to complete all the study treatments. ☐ yes ☐ no

Exclusion Criteria: All responses must be NO for participant to be eligible. The participant must NOT:

1. Have a current or past history of seizure disorder, including alcohol- or stimulant-related seizure, febrile seizure, or significant family history of idiopathic seizure disorder. ☐ yes ☐ no
2. Have any previous medically adverse reaction to cocaine, including loss of consciousness, chest pain, or seizure. ☐ yes ☐ no
3. According to DSM-IV criteria as determined by structured clinical interview (SCID), have any history of major psychiatric illness other than ADHD, drug dependence or disorders secondary to drug use. ☐ yes ☐ no

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INCLUSION/EXCLUSION CRITERIA

Exclusion Criteria: All responses must be NO for participant to be eligible. The participant must NOT:

4. If female, be pregnant or nursing. ☐ yes ☐ no
5. Have a history of liver disease or current elevation of aspartate aminotransferase (AST) or alanine aminotransferase (ALT) exceeding the upper limit of normal. ☐ yes ☐ no
6. Have donated a unit of blood or participated in any other clinical investigation involving cocaine administration within 4 weeks of enrolling in the study. ☐ yes ☐ no
7. Have a history of any illness, or a family history of early significant cardiovascular disease, or a history of behavior, that in the opinion of the investigator might confound the results of the study or pose additional risk in administering the investigational agents to the subject. ☐ yes ☐ no
8. Be seropositive for hepatitis B surface antigen, hepatitis C antibody, or human immunodeficiency virus (HIV) type 1. ☐ yes ☐ no
9. Have a diagnosis of adult (i.e., 21 years or older) asthma, or chronic obstructive pulmonary disease (COPD), including those with a history of acute asthma within the past two years, and those with current or recent (past 2 years) treatment with inhaled or oral beta-agonist. ☐ yes ☐ no
10. Have any illness, condition, and use of medications, that in the opinion of the Principal Investigator and the admitting physician, would preclude safe and/or successful completion of the study. ☐ yes ☐ no
11. Currently use illicit drugs besides cocaine and marijuana. ☐ yes ☐ no
12. Have used any prescription drugs within 14 days of the start of the study or non-prescription drugs within 7 days of the start of the study. ☐ yes ☐ no
13. Be unable to distinguish between a 20 mg and 40 mg dose of cocaine intravenously during the administration of baseline infusions as manifested by a higher score on the Visual Analog Scale and increase in heart rate after the 40 mg dose of cocaine compared to the 20mg dose. ☐ yes ☐ no
14. Be physiologically dependent on alcohol requiring medical detoxification. ☐ yes ☐ no

Completed by (initials):



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National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

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☐

Not Done

SCREENING INFUSION MONITORING

Study Day: ● -6 (Sessions 1 & 2)

Screening Infusions Date:

/ / 20

mm / dd / yyyy

Time Interval	Actual Time (00:00-23:59)	Blood Pressure (sys/dias)	Heart Rate (beats/min)
-75 min	:	/	
-70 min	:	/	
-65 min	:	/	

Saline Infusion
Start Time

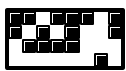
:

Administered By:

Saline Infusion
Stop Time

:

-58 min	:	/	
-56 min	:	/	
-54 min	:	/	
-52 min	:	/	
-50 min	:	/	
-45 min	:	/	
-40 min	:	/	
-35 min	:	/	
-30 min	:	/	
-25 min	:	/	
-20 min	:	/	
-15 min	:	/	
-10 min	:	/	
-5 min	:	/	



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National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

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site #

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subject #

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SCREENING INFUSION MONITORING

SESSION 1

20 mg Infusion
Start Time

: :

Administered By:

: :

20 mg Infusion
Stop Time

: :

+2 min

: :

/

: :

: :

4 min

: :

/

: :

: :

6 min

: :

/

: :

: :

8 min

: :

/

: :

: :

10 min

: :

/

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: :

15 min

: :

/

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: :

20 min

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/

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: :

25 min

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/

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: :

30 min

: :

/

: :

: :

35 min

: :

/

: :

: :

40 min

: :

/

: :

: :

45 min

: :

/

: :

: :

50 min

: :

/

: :

: :

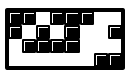
55 min

: :

/

: :

: :



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subject #

Protocol #

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SCREENING INFUSION MONITORING

SESSION 2

40 mg Infusion

Start Time

:

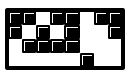
Administered By:

40 mg Infusion

Stop Time

:

Time Interval	Actual Time (00:00-23:59)	Blood Pressure (sys/dias)	Heart Rate (beats/min)
62 min	:	/	
64 min	:	/	
66 min	:	/	
68 min	:	/	
70 min	:	/	
75 min	:	/	
80 min	:	/	
85 min	:	/	
90 min	:	/	
95 min	:	/	
100 min	:	/	
110 min	:	/	
115 min	:	/	
120 min	:	/	



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site #

-

subject #

Protocol #

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- CPU

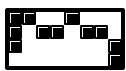
- ATOMOXETINE

- 0001

SCREENING INFUSION MONITORING

Time Interval	Actual Time (00:00-23:59)		Blood Pressure (sys/dias)				Heart Rate (beats/min)		
150 min	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>
180 min	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>
210 min	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>
240 min	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>
270 min	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>
300 min	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>
330 min	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>
360 min	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>

Completed by (initials):



46721

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA - CPU - ATOMOXETINE - 0001

☐ Not Done

INFUSION MONITORING

☐ -2 (Session 3)☐ 8 (Session 6)Study Day: ☐ -1 (Session 4)☐ 12 (Session 7)

Infusion Date:

/ / 20

☐ 7 (Session 5)☒ 13 (Session 8)

mm / dd / yyyy

Time Interval	Actual Time (00:00-23:59)	Blood Pressure (sys/dias)	Heart Rate (beats/min)
-15 min	:	/	
-10 min	:	/	
-5 min	:	/	

1st Infusion
Start Time

:

Administered By:

1st Infusion
Stop Time

:

+2 min	:	/	
4 min	:	/	
6 min	:	/	
8 min	:	/	
10 min	:	/	
15 min	:	/	
20 min	:	/	
25 min	:	/	
30 min	:	/	
35 min	:	/	
40 min	:	/	
45 min	:	/	
50 min	:	/	
55 min	:	/	



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National Institute on Drug Abuse

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site #

-

subject #

Protocol #

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INFUSION MONITORING

2nd Infusion
Start Time

:

Administered By:

2nd Infusion
Stop Time

:

Time Interval	Actual Time (00:00-23:59)	Blood Pressure (sys/dias)	Heart Rate (beats/min)
62 min	:	/	
64 min	:	/	
66 min	:	/	
68 min	:	/	
70 min	:	/	
75 min	:	/	
80 min	:	/	
85 min	:	/	
90 min	:	/	
95 min	:	/	
100 min	:	/	
110 min	:	/	
115 min	:	/	
120 min	:	/	



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Subject ID

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site #

-

subject #

Protocol #

NIDA - CPU - ATOMOXETINE - 0001

INFUSION MONITORING

Time Interval	Actual Time (00:00-23:59)	Blood Pressure (sys/dias)	Heart Rate (beats/min)
150 min	:	/	
180 min	:	/	
210 min	:	/	
240 min	:	/	
270 min	:	/	
300 min	:	/	
330 min	:	/	
360 min	:	/	

Completed by (initials):



22502

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA - CPU - ATOMOXETINE - 0001

INFUSION RANDOMIZATION

INSTRUCTIONS: Complete and fax to TRI within 24 hours of event occurring.

Date of Infusion Randomization:

/

/

20

mm / dd / yyyy

Randomization #

Completed by (initials):

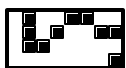
Date completed

/

/

20

mm / dd / yyyy



21344

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA - CPU - ATOMOXETINE - 0001

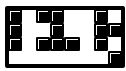
☐

Not Done

INVESTIGATIONAL AGENT ADMINISTRATION

STUDY DAY	DATE (mm/dd/yyyy)	Number of caplets administered	Time administered (00:00-23:59)	Administered by (initials)
0	/ / 20		:	
1	/ / 20		:	
2	/ / 20		:	
3	/ / 20		:	
4	/ / 20		:	
5	/ / 20		:	
6	/ / 20		:	
7	/ / 20		:	
8	/ / 20		:	
9	/ / 20		:	
10	/ / 20		:	
11	/ / 20		:	
12	/ / 20		:	
13	/ / 20		:	

Completed by (initials):



37818

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA

- CPU

- ATOMOXETINE

- 0001

INVESTIGATOR'S ACCOUNTABILITY AND SIGNATURE

By my signature below, I attest that I am the Investigator listed on FDA Form 1572 and that I have reviewed and attest to the accuracy of all the data recorded on the CRFs herein and any Supplemental forms and supporting documents.

I understand that questions may result from the Sponsor's review of these case report forms. These questions may result from missing, unclear or incorrect entries. I understand that it will be necessary for me or my staff to make the appropriate corrections to the case report forms. By my signature below, I authorize my subinvestigator(s) or other approved staff to make necessary corrections. I understand that I am ultimately responsible for any corrections made by my staff.

Date

mm

/ dd

/ 20

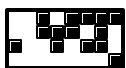
mm

mm / dd / yyyy

Investigator's signature

Principal Investigator:

(Last Name, First Name)



14998

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA

- CPU

- ATOMOXETINE

- 0001

☐ Not Done

MEDICAL HISTORY

Study Day: ● Pre-Intake Screening

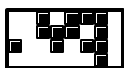
Assessment Date

/ / 20

mm / dd / yyyy

Mark one answer for each disorder. Mark "Yes excludes" if subject has condition that excludes him/her from study participation. Mark "Yes doesn't exclude" if subject has condition that does not exclude him/her from study participation. Mark "No history of disorder" if subject has not ever had condition. Mark "Not evaluated" if not evaluated or unknown.

Disorder:	*Yes excludes	No doesn't exclude	history of disorder	Not evaluated	*If Yes, specify or describe
1. allergies: drug	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
2. allergies: other, specify <input type="text"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
3. sensitivity to investigational agent or related compounds	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
4. history of asthma	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
5. head, ears, eyes, nose, throat (HEENT)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
6. cardiovascular	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
7. renal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
8. hepatic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
9. pulmonary	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
10. gastrointestinal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
11. musculoskeletal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
12. neurologic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
13. psychiatric	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
14. dermatologic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
15. metabolic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
16. hematologic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	



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-

subject #

Protocol #

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MEDICAL HISTORY

Disorder:

*Yes
excludes

*Yes
doesn't
exclude

No
history of
disorder

Not
evaluated

*If Yes, specify or describe

17. endocrine

☐☐☐☐

18. genitourinary

☐☐☐☐

19. reproductive system

☐☐☐☐

20. seizure

☐☐☐☐

21. infectious disease

☐☐☐☐

22. other1, specify

☐☐

23. other2, specify

☐☐

24. Was major surgery ever performed?

☐ Yes☐ No

If Yes, list surgeries:

Type of Surgery

Date of Surgery

mm

dd

yyyy

Yes
excludesNo
doesn't
exclude

25.

/

/

☐☐

26.

/

/

☐☐

27.

/

/

☐☐**Tobacco History**

28. Has subject used any tobacco product (e.g. cigarettes, cigars, pipe, chewing tobacco) in the past week?

☐ Yes☐ No

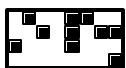
29. Has subject ever used any tobacco product for at least one year?

☐ Yes☐ No

30. If yes, number of years tobacco used?

Additional Comments (optional):

Completed by (initials):



11144

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Subject ID

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subject #

Protocol #

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- 0001

☐ Not Done

PHYSICAL EXAM

Study Day: ☐ Pre-intake Screening☐ 17 (Discharge)☒ Follow Up (Week 2)

Exam Date

/ / 20

mm / dd / yyyy

Height

/ /

inches

Weight

/ /

pounds

Indicate whether the physical exam reveals a body system is **NORMAL**: no physical problems, **ABNORMAL**: but does not affect enrollment or continued study participation, **ABNORMAL SIGNIFICANT**: significant during screening means subject is ineligible for study.

	normal	abnormal	abnormal significant	not done	Provide comments for any abnormal finding.
Oral (mouth)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Head and neck	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Eyes, ears, nose/throat	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Cardiovascular	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Chest	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Lungs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Abdomen (include liver/spleen)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Extremities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Skin, hair, nails	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Neuropsychiatric mental status	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Neuropsychiatric sensory/motor	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Musculoskeletal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
General appearance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Other (specify)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
Other (specify)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		

Completed by (initials):

/ /



40114

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA - CPU - ATOMOXETINE - 0001

☐

Not Done

PROFILE OF MOOD STATUS (POMS) - Inpatient

Inpatient study day:

Assessment Date

 / / 20

mm / dd / yyyy

Instructions: Transcribe from POMS source document the number circled for each adjective.

1. Friendly

17. Grouchy

33. Resentful

2. Tense

18. Blue

34. Nervous

3. Angry

19. Energetic

35. Lonely

4. Worn out

20. Panicky

36. Miserable

5. Unhappy

21. Hopeless

37. Muddled

6. Clear-headed

22. Relaxed

38. Cheerful

7. Lively

23. Unworthy

39. Bitter

8. Confused

24. Spiteful

40. Exhausted

9. Sorry for things

25. Sympathetic

41. Anxious

10. Shaky

26. Uneasy

42. Ready to fight

11. Listless

27. Restless

43. Good natured

12. Peeved

28. Unable to concentrate

44. Gloomy

13. Considerate

29. Fatigued

45. Desperate

14. Sad

30. Helpful

46. Sluggish

15. Active

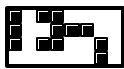
31. Annoyed

47. Rebellious

16. On edge

32. Discouraged

48. Helpless



40114

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PROFILE OF MOOD STATUS (POMS) - Inpatient

☐

49. Weary

☐

50. Bewildered

☐

51. Alert

☐

52. Deceived

☐

53. Furious

☐

54. Efficient

☐

55. Trusting

☐

56. Full of pep

☐

57. Bad-tempered

☐

58. Worthless

☐

59. Forgetful

☐

60. Carefree

☐

61. Terrified

☐

62. Guilty

☐

63. Vigorous

☐

64. Uncertain about things

☐

65. Bushed

Completed by (initials):



21319

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

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site #

- [] [] [] []

subject #

Protocol #

NIDA - CPU - ATOMOXETINE - 0001

☐

Not Done

PROFILE OF MOOD STATUS (POMS)

Study Day: ● Intake Screening

Assessment Date

[] [] / [] [] / 20 [] []

mm / dd / yyyy

Instructions: Transcribe from POMS source document the number circled for each adjective.☐

1. Friendly

☐

17. Grouchy

☐

33. Resentful

☐

2. Tense

☐

18. Blue

☐

34. Nervous

☐

3. Angry

☐

19. Energetic

☐

35. Lonely

☐

4. Worn out

☐

20. Panicky

☐

36. Miserable

☐

5. Unhappy

☐

21. Hopeless

☐

37. Muddled

☐

6. Clear-headed

☐

22. Relaxed

☐

38. Cheerful

☐

7. Lively

☐

23. Unworthy

☐

39. Bitter

☐

8. Confused

☐

24. Spiteful

☐

40. Exhausted

☐

9. Sorry for things

☐

25. Sympathetic

☐

41. Anxious

☐

10. Shaky

☐

26. Uneasy

☐

42. Ready to fight

☐

11. Listless

☐

27. Restless

☐

43. Good natured

☐

12. Peeved

☐

28. Unable to concentrate

☐

44. Gloomy

☐

13. Considerate

☐

29. Fatigued

☐

45. Desperate

☐

14. Sad

☐

30. Helpful

☐

46. Sluggish

☐

15. Active

☐

31. Annoyed

☐

47. Rebellious

☐

16. On edge

☐

32. Discouraged

☐

48. Helpless



21319

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

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-

subject #

Protocol #

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- 0001

PROFILE OF MOOD STATUS (POMS)

☐

49. Weary

☐

50. Bewildered

☐

51. Alert

☐

52. Deceived

☐

53. Furious

☐

54. Efficient

☐

55. Trusting

☐

56. Full of pep

☐

57. Bad-tempered

☐

58. Worthless

☐

59. Forgetful

☐

60. Carefree

☐

61. Terrified

☐

62. Guilty

☐

63. Vigorous

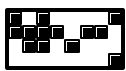
☐

64. Uncertain about things

☐

65. Bushed

Completed by (initials):



63080

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA - CPU - ATOMOXETINE - 0001

☐ Not Done

PREGNANCY TEST

Study Day: ☐ Pre-Intake Screening☐ Within 72 hrs of Day -6 (Session 1)☐ 13 (Session 8)☐ 17 (Discharge)☒ Follow Up (Week 2)

Test Date

/ / 20

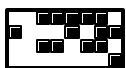
mm / dd / yyyy

Pregnancy test result:

☐ Positive☐ Negative☐ Unknown

Pregnancy test comments:

Completed by (initials):



35638

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Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA

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STUDY DRUG RANDOMIZATION

INSTRUCTIONS: Complete and transcribe onto CRF. Fax CRF to TRI within 24 hours of event occurring.

Is participant still eligible for participation based on the Eligibility Criteria?
(required field)

☐ yes☐ no

Date of study drug randomization:

/ /

mm / dd / yyyy

Randomization #

Completed by (initials):

Date completed

/ / 20

mm / dd / yyyy



44246

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

9	9	0	1	0	1
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 -

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 Protocol #

N	I	D	A
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 -

C	P	U
---	---	---

 -

A	T	O	M	O	X	E	T	I	N	E
---	---	---	---	---	---	---	---	---	---	---

 -

0	0	0	1
---	---	---	---

site # subject #

☐ Not Done

SERIOUS ADVERSE EVENT

INSTRUCTIONS: Complete and fax to TRI within 24 hours of event occurring.

SAE Report: ☐ Initial Report
☐ Follow up Report
Follow up Report #

--

 (i.e. 1, 2, 3)

DEMOGRAPHIC INFORMATION

Gender: ☐ Male ☐ Female

Date of Birth:

--	--

 /

--	--

 /

--	--	--	--

 mm / dd / yyyy

Height

--	--	--

 inches Weight

--	--	--

 pounds

Race

- ☐ Spanish, Hispanic, or Latino
☐ American Indian or Alaska Native
☐ Asian
☐ Black, African American
☐ Native Hawaiian or Pacific Islander
☐ White
☐ Other, specify

--

☐ Unknown/Participant chooses not to answer

SERIOUS ADVERSE EVENT

Name of Event: (clinical diagnosis if possible)

--

Description of Event: (include any test results, x-rays, relevant medical history, physical findings, interventions done)

--

Onset date

--	--

 /

--	--

 /

2	0		
---	---	--	--

 mm / dd / yyyy

SAE resolution date*

--	--

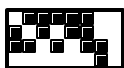
 /

--	--

 /

2	0		
---	---	--	--

 mm / dd / yyyy



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Subject ID

990101

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-

subject #

Protocol #

NIDA-CPU-ATOMOXETINE-0001

SERIOUS ADVERSE EVENT

Reason(s) adverse event is reported as serious

- ☐ Death* *If outcome was death, a Death Report Case Report Form must be completed.
- ☐ Life Threatening
- ☐ Hospitalization (initial or prolonged)
- ☐ Persistent or significant disability/incapacity
- ☐ Congenital anomaly/birth defect
- ☐ Anomaly
 - ☐ Miscarriage
 - ☐ Aborted
 - ☐ Stillbirth
 - ☐ Infant death within one month of life
- ☐ Required intervention to prevent permanent impairment/damage
- ☐ Other, specify

SAE Expectedness

- ☐ Unexpected ☐ Expected

Severity grade

- ☐ Mild ☐ Moderate ☐ Severe

Was SAE related to investigational agent?

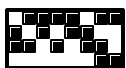
- ☐ Definitely ☐ Probably ☐ Possibly ☐ Definitely not ☐ Unknown

Action taken regarding investigational agent

- ☐ None
- ☐ Discontinued permanently
- ☐ Discontinued temporarily
- ☐ Reduced dose
- ☐ Increased dose
- ☐ Delayed dose
- ☐ Continued dose
- ☐ Unknown

Outcome of SAE

- ☐ Recovered/Resolved
- ☐ Recovering/Resolving
- ☐ Not Recovered/Not Resolved
- ☐ Recovered/Resolved with sequelae
- ☐ Fatal, date of death / / mm / dd / yyyy



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National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

9	9	0	1	0	1
---	---	---	---	---	---

 -

--	--	--	--

 Protocol #

N	I	D	A
---	---	---	---

 -

C	P	U
---	---	---

 -

A	T	O	M	O	X	E	T	I	N	E
---	---	---	---	---	---	---	---	---	---	---

 -

0	0	0	1
---	---	---	---

site # subject #

SERIOUS ADVERSE EVENT

INVESTIGATIONAL AGENT ADMINISTRATION

Is investigational agent information known? ☐ yes ☐ no (if no, skip down to other actions taken)

Investigational Agent name (if known)

Investigational Agent Lot Number

Investigational Agent Expiration Date

--	--

 /

--	--

 /

2	0		
---	---	--	--

Investigational Agent Dose

Investigational Agent Unit

Investigational Agent Frequency

Investigational Agent Route

Investigational Agent Start Date

--	--

 /

--	--

 /

2	0		
---	---	--	--

Investigational Agent Stop Date

--	--

 /

--	--

 /

2	0		
---	---	--	--

OTHER ACTION TAKEN

Action taken for informed consent

- ☐ None
☐ Changed consent form
☐ Unknown

Action taken for protocol

- ☐ None
☐ Changed protocol
☐ Unknown



Subject ID 990101 - Protocol # NIDA - CPU - ATOMOXETINE - 0001

Relevant tests/laboratory data, including dates

--

Relevant history including pre-existing medical conditions (e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

[illegible]

Additional Comments

--

Sponsor Notified: ☐ No ☐ Yes Date: / /

Local IRB Notified: ☐ No ☐ Yes Date: / /

NIDA Medical Monitor Notified ☐ No ☐ Yes Date: / /

ADDRESS SAE QUESTIONS TO THE FOLLOWING CLINICAL STAFF MEMBER:

Name
(please print)

--

Phone

--

Email

Principal Investigator:

[illegible]

(Last Name, First Name)

Investigator's signature

Date PI signed:			/			/			
-----------------	--	--	---	--	--	---	--	--	--

Completed by (initials):

--	--	--

Date Completed:

--	--	--	--

mm / dd / yyyy



12338

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA - CPU - ATOMOXETINE - 0001

☐ Not Done**SCID**

Study Day: ● Intake Screening

Assessment Date

/ / 20

mm / dd / yyyy

INSTRUCTIONS: Please list all CURRENT and PAST Substance abuse or Dependence Diagnoses, other current and other past diagnoses (include DSM-IV code).

Axis 1 Diagnoses Type

- 1= Current Diagnoses Substance Abuse or Dependence
- 2= Past Diagnoses Substance Abuse or Dependence
- 3= Other Current Diagnoses
- 4= Other Past Diagnoses

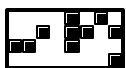
Line #

Axis 1
Diagnoses Type
(use legend above)DSM-IV
Code

Diagnosis

1

Completed by (initials):



11720

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA - CPU - ATOMOXETINE - 0001

SCREENING

INSTRUCTIONS: Complete and fax to TRI within 24 hours of event occurring.

Date subject signed informed consent:

/

mm / dd / yyyy

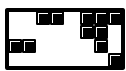
Completed by (initials):

Date form completed

/

/ 20

mm / dd / yyyy



1730

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA - CPU - ATOMOXETINE - 0001

☐ Not Done

TIMELINE FOLLOW BACK-Intake

Study Day: ● Pre-Intake Screening

Assessment Date

/ /

mm / dd / yyyy

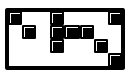
INSTRUCTIONS: Transcribe responses from Timeline follow back source document. Treat Day 30 as yesterday.

Day 1 (30 days ago) / /

Day 30 (yesterday) / /

Day 1 ☐ yes ☐ noDay 15 ☐ yes ☐ noDay 29 ☐ yes ☐ noDay 2 ☐ yes ☐ noDay 16 ☐ yes ☐ noDay 30 (yesterday) ☐ yes ☐ no☐ ☐☐ ☐Day 4 ☐ yes ☐ noDay 18 ☐ yes ☐ no☐ ☐☐ ☐Day 6 ☐ yes ☐ noDay 20 ☐ yes ☐ no☐ ☐☐ ☐Day 8 ☐ yes ☐ noDay 22 ☐ yes ☐ no☐ ☐☐ ☐Day 10 ☐ yes ☐ noDay 24 ☐ yes ☐ no☐ ☐☐ ☐Day 12 ☐ yes ☐ noDay 26 ☐ yes ☐ no☐ ☐☐ ☐Day 14 ☐ yes ☐ noDay 28 ☐ yes ☐ no

Completed by (initials):



23570

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA

- CPU

- ATOMOXETINE

- 0001

☐

Not Done

URINALYSIS

Study Day: ● Pre-Intake Screening

Test Date

/ /

mm / dd / yyyy

INSTRUCTIONS: Indicate whether the laboratory value is **NORMAL**: within normal limits, **ABNORMAL**: outside of normal limits but not clinically significant, **ABNORMAL SIGNIFICANT**: significant during screening means subject is ineligible for study; significant while on study means it should be reported as an adverse event.

Dipstick Urinalysis:

Specific gravity

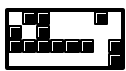
.

pH

.

	0	trace	1+	2+	3+	4+	normal	abnormal	abnormal significant	not done	Provide comments for any abnormal value.
Blood	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Protein	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Glucose	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Ketones	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Leukocytes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Nitrite	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Completed by (initials):



41213

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA - CPU

- ATOMOXETINE

- 0001

☐ Not Done

URINE TOXICOLOGY

INSTRUCTIONS: Bubble in study day and complete assessment date in mm/dd/yyyy format.

Inpatient study day:

(i.e -4, 3, 23)

Test Date

 / /

mm / dd / yyyy

Urine temperature within expected range?

 $(96.4 \geq T \leq 100.4 \text{ }^{\circ}\text{F})$ ☐ Yes☐ No☐ Unknown

	Positive	Negative	Not done
Amphetamines	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Barbiturates	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Benzodiazepines	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cannabinoids (THC)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Cocaine metabolites	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Methadone	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Methamphetamine	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Methaqualone	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Opiates	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Phencyclidine (PCP)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Propoxyphene	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Completed by (initials):



44650

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA - CPU

- ATOMOXETINE

- 0001

☐ Not Done

URINE TOXICOLOGY

INSTRUCTIONS: Bubble in study day and complete assessment date in mm/dd/yyyy format.Study Day: ☐ Pre-Intake Screening☐ Intake Screening☐ 17 (Discharge)☒ Follow up (Week 2)

Test Date

/ /

mm / dd / yyyy

Urine temperature within expected range?

 $(96.4 \geq T \leq 100.4 \text{ }^{\circ}\text{F})$ ☐ Yes☐ No☐ Unknown

Positive

Negative

Not done

Amphetamines

☐☐☐

Barbiturates

☐☐☐

Benzodiazepines

☐☐☐

Cannabinoids (THC)

☐☐☐

Cocaine metabolites

☐☐☐

Methadone

☐☐☐

Methamphetamine

☐☐☐

Methaqualone

☐☐☐

Opiates

☐☐☐

Phencyclidine (PCP)

☐☐☐

Propoxyphene

☐☐☐

Completed by (initials):

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID	990101	-		Protocol #	NIDA	-	CPU	-	ATOMOXETINE	-	0001
	site #		subject #								

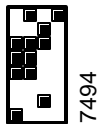
☐ Not Done

SCREENING VISUAL ANALOG SCALE(VAS)

Study Day: ● -6 (Sessions 1 & 2)

Instructions: Transcribe responses from VAS. Complete actual time assessment administered. For each question, measure response using ruler printed on transparent film. Lay film over bar to calculate corresponding numerical value and transfer to CRF.

Time Interval	Actual Time (00:00-23:59)	Any drug effect?	High?	Good effects?	Bad effects?	Liking?	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
-75 min (15 min pre saline infusion)	:											
Saline Infusion												
-55 min (5 min post saline infusion)	:											
	:											
	:											
	:											



7494

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

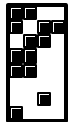
subject #

Protocol #

NIDA - CPU - ATOMOXETINE - 0001

SCREENING VISUAL ANALOG SCALE(VAS)

Time Interval	Actual Time (00:00-23:59)	Any drug effect?	High?	Good effects?	Bad effects?	Liking?	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
-15 min (15 min pre 20mg infusion)	:											
20mg Infusion												
5 min (5 min post 20mg infusion)	:											
15 min (15 min post 20mg infusion)	:											
25 min (25 min post 20mg infusion)	:											
35 min (35 min post 20mg infusion)	:											



7494

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA

- CPU

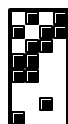
- ATOMOXETINE

- 0001

SCREENING VISUAL ANALOG SCALE(VAS)

Time Interval	Actual Time (00:00-23:59)	Any drug effect?	High?	Good effects?	Bad effects?	Liking?	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
45 min (-15 min pre 40mg infusion)	:											
40mg Infusion												
65 min (5 min post 40mg infusion)	:											
75 min (15 min post 40mg infusion)	:											
85 min (25 min post 40mg infusion)	:											
95 min (35 min post 40mg infusion)	:											

Completed by (initials):

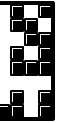


7494

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

26843



Subject ID

9 9 0 1 0 1

site #

-

subject #

Protocol #

N I D A - C P U - A T O M O X E T I N E - 0 0 0 1

☐ Not Done

VISUAL ANALOG SCALE(VAS)

Study Day: ☐ -2 (Session 3) ☐ 8 (Session 6)
☐ -1 (Session 4) ☐ 12 (Session 7)
☐ 7 (Session 5) ☒ 13 (Session 8)

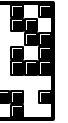
Instructions: Transcribe responses from VAS. Complete actual time assessment administered. For each question, measure response using ruler printed on transparent film. Lay film over bar to calculate corresponding numerical value and transfer to CRF.

Time Interval	Actual Time (00:00-23:59)	Any drug effect?	High?	Good effects?	Bad effects?	Liking?	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
-15 min	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
1st Infusion												
5 min	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
15 min	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
25 min	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
35 min	<input type="text"/> : <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

26843



Subject ID

9 9 0 1 0 1

site #

- [] [] [] []

subject #

Protocol #

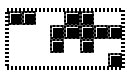
N I D A - C P U - A T O M O X E T I N E - 0 0 0 1

VISUAL ANALOG SCALE(VAS)

Time Interval	Actual Time (00:00-23:59)	Any drug effect?	High?	Good effects?	Bad effects?	Liking?	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
45 min (-15 min before 2nd infusion)	[][] : [][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][][]
2nd Infusion												
65 min (5 min post 2nd infusion)	[][] : [][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][][]
75 min (15 min post 2nd infusion)	[][] : [][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][][]
85 min (25 min post 2nd infusion)	[][] : [][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][][]
95 min (35 min post 2nd infusion)	[][] : [][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][]	[][][][]

Completed by (initials):

[][] [][]



7956

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - Protocol # NIDA - CPU - ATOMOXETINE - 0001
site # subject #

☐ Not Done

VITAL SIGNS

INSTRUCTIONS: Bubble in study day and complete assessment date in mm/dd/yyyy format.

Study Day: ☐ Pre-Intake Screening

☐ Intake Screening

☐ 17 (Discharge)

☒ 31 (Follow Up)

Assessment Date

/ /
mm / dd / yyyy

Time vital signs taken

:

(00:00-23:59)

Temperature (oral)

.

°F

☐ Not done

Respiratory rate

breaths/minute

☐ Not done

Blood pressure- sitting
(systolic / diastolic)

/

mm Hg

☐ Not done

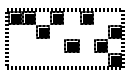
Pulse rate-sitting

beats/minute

☐ Not done

Comments:

Completed by (initials):



8458

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID

990101

site #

-

subject #

Protocol #

NIDA - CPU - ATOMOXETINE - 0001

☐ Not Done

VITAL SIGNS

INSTRUCTIONS: Bubble in study day and complete assessment date in mm/dd/yyyy format.

Inpatient study day:

(i.e -4, 3, 23)

Assessment Date

 / /

mm / dd / yyyy

Time vital signs taken

 :

(00:00-23:59)

Temperature (oral)

 .

°F

☐ Not done

Respiratory rate

breaths/minute

☐ Not doneBlood pressure- sitting
(systolic / diastolic) /

mm Hg

☐ Not done

Pulse rate-sitting

beats/minute

☐ Not done

Comments:

Completed by (initials):