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	B. STUDY DRUG RELATIONSHIP	C. ACTION TAKEN REGARDING INVESTIGATIONAL AGENT	D. OUTCOME OF AE
1 = Mild 2 = Moderate 3 = Severe	1 = Definitely 2 = Probably 3 = Possibly 4 = Remotely 5 = Definitely Not 6 = Unknown	1 = None 2 = Discontinued Perm. 3 = Discontinued Temp. 4 = Reduced Dose 5 = Increased Dose 6 = Delayed Dose 7 = Continued Dose 8 = Unknown	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?
	/ /	/ /					⬭ yes* ⬭ no
	/ /	/ /					⬭ yes* ⬭ no
	/ /	/ /					⬭ yes* ⬭ no
	/ /	/ /					⬭ yes* ⬭ no
	/ /	/ /					⬭ yes* ⬭ no
	/ /	/ /					⬭ yes* ⬭ no

*If yes, complete SAE form.

Completed by (initials): ____ Date completed ____ / ____ / 20____ mm / dd / yyyy Page ____ of ____

25005

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID ☐☐☐☐☐☐ – ☐☐☐☐ **Protocol #** ☐☐☐ - ☐☐☐ - ☐☐☐☐☐☐☐☐☐☐ - ☐☐☐☐
site # subject #

☐ Not Done

PLASMA ALCOHOL TEST

Study Day: ⬭ Intake Screening

Test Date ☐☐ / ☐☐ / ☐☐☐☐
mm / dd / yyyy

Is result less than 10 mg/dL ⬭ **YES** ⬭ **NO**

If no, please record result ☐☐☐.☐ mg/dL

Completed by (initials): ☐☐☐

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - [ ][ ][ ][ ] (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

☐ Not Done

BREATHALYZER ALCOHOL TEST

Study Day: ● Intake Screening

Test Date [ ][ ] / [ ][ ] / 20[ ][ ] (mm / dd / yyyy)

Alchohol Breathalyzer Result: 0.[ ][ ][ ] mg/mL

Comments:

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

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - [site #] [subject #] **Protocol #** NIDA-CPU-ATOMOXETINE-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	25. Pleasant emptiness
○ True	○ False	2. Not as active as usual	○ True	○ False	26. Thoughts come easier
○ True	○ False	3. Feeling of dragging	○ True	○ False	27. Less discouraged
○ True	○ False	4. Feel sluggish	○ True	○ False	28. Mood to talk
○ True	○ False	5. Head feels heavy	○ True	○ False	29. More excited
○ True	○ False	6. Feel like avoiding	○ True	○ False	30. Answering was easy
○ True	○ False	7. Feel dizzy	○ True	○ False	31. Memory sharper
○ True	○ False	8. Harder to move around	○ True	○ False	32. Could write for hours
○ True	○ False	9. I am moody	○ True	○ False	33. Very patient
○ True	○ False	10. I am a little dull	○ True	○ False	34. Body is tingling
○ True	○ False	11. I feel drowsy	○ True	○ False	35. Have weird feeling
○ True	○ False	12. I am full of energy	○ True	○ False	36. Movements faster
○ True	○ False	13. Say things easiest	○ True	○ False	37. Movements slower
○ True	○ False	14. Things more pleasing	○ True	○ False	38. Better control
○ True	○ False	15. Pleasant feelings	○ True	○ False	39. Mind on task
○ True	○ False	16. Lose contentment	○ True	○ False	40. Don't like reading
○ True	○ False	17. Complete harmony	○ True	○ False	41. Spending longer
○ True	○ False	18. Appreciate saying	○ True	○ False	42. Hands feel clumsy
○ True	○ False	19. Happy all the time	○ True	○ False	43. Hands shake
○ True	○ False	20. So good others know	○ True	○ False	44. Disturbed stomach
○ True	○ False	21. Something pleasant	○ True	○ False	45. Bodily sensations
○ True	○ False	22. Be happy all the time	○ True	○ False	46. Anxious and upset
○ True	○ False	23. More clear headed	○ True	○ False	47. Weakness of muscles
○ True	○ False	24. More popular	○ True	○ False	48. Thrill through me
			○ True	○ False	49. Movements are free

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

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - ____ (site # / subject #) **Protocol #** 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 #5, 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: _____

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - ____ (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

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

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - ____ (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

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: _____

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - ____ (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

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			○				
2. Alcohol - to intoxication			○				
3. Heroin			○	○	○	○	○
4. Methadone			○	○	○	○	○
5. Other opiates/analgesics			○	○	○	○	○
6. Barbiturates			○	○	○	○	○
7. Sedatives/hypnotics/tranquilizers			○	○	○	○	○
8. Cocaine			○	○	○	○	○
9. Amphetamines			○	○	○	○	○
10. Cannabis			○	○	○		
11. Hallucinogens			○	○	○	○	○
12. Inhalants			○	○			
13. More than one substance per day (including alcohol)							

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - ____ (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

ADDICTION SEVERITY INDEX: LITE

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

Subject ID 990101 - ____ (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

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

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - ____ (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

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

Subject ID 990101 - ____ (site # / subject #) Protocol # NIDA-CPU-ATOMOXETINE-0001

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

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - ____ (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

ADDICTION SEVERITY INDEX: LITE

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	○	○	○	○	○	○	○	○
10. Father	○	○	○	○	○	○	○	○
11. Siblings	○	○	○	○	○	○	○	○
12. Sexual partner/spouse	○	○	○	○	○	○	○	○
13. Children	○	○	○	○	○	○	○	○
14. Other significant family	○	○	○	○	○	○	○	○
15. If 14 is yes, specify:								
16. Close Friends	○	○	○	○	○	○	○	○
17. Neighbors	○	○	○	○	○	○	○	○
18. Co-workers	○	○	○	○	○	○	○	○

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - ____ (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

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: ____

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - ____ (site # / subject #) Protocol # NIDA-CPU-ATOMOXETINE-0001

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

Subject ID 990101 - ____ (site # / subject #)

Protocol # NIDA-CPU-ATOMOXETINE-0001

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): ___

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - [ ][ ][ ][ ] **Protocol #** NIDA-CPU-ATOMOXETINE-0001

site # subject #

☐ Not Done

ATOMOXETINE PK

Study Day:
- ● 6
- ○ 8 (Session 6)
- ○ 11
- ○ 13 (Session 8)

Lab Date [ ][ ] / [ ][ ] / 20[ ][ ]
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 - [ ][ ][ ][ ] **Protocol #** NIDA-CPU-ATOMOXETINE-0001

site # subject #

☐ 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	[ ] 13. Self-neglect
[ ] 2. Anxiety	[ ] 14. Disorientation
[ ] 3. Depression	[ ] 15. Conceptual Disorganization
[ ] 4. Suicidality	[ ] 16. Blunted Affect
[ ] 5. Guilt	[ ] 17. Emotional Withdrawal
[ ] 6. Hostility	[ ] 18. Motor Retardation
[ ] 7. Elevated Mood	[ ] 19. Tension
[ ] 8. Grandiosity	[ ] 20. Uncooperativeness
[ ] 9. Suspiciousness	[ ] 21. Excitement
[ ] 10. Hallucinations	[ ] 22. Distractibility
[ ] 11. Unusual Thought Content	[ ] 23. Motor Hyperactivity
[ ] 12. Bizarre Behavior	[ ] 24. Mannerisms and Posturing

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

5370

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - [ ][ ][ ][ ] **Protocol #** NIDA-CPU-ATOMOXETINE-0001
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	☐ 13. Self-neglect
☐ 2. Anxiety	☐ 14. Disorientation
☐ 3. Depression	☐ 15. Conceptual Disorganization
☐ 4. Suicidality	☐ 16. Blunted Affect
☐ 5. Guilt	☐ 17. Emotional Withdrawal
☐ 6. Hostility	☐ 18. Motor Retardation
☐ 7. Elevated Mood	☐ 19. Tension
☐ 8. Grandiosity	☐ 20. Uncooperativeness
☐ 9. Suspiciousness	☐ 21. Excitement
☐ 10. Hallucinations	☐ 22. Distractibility
☐ 11. Unusual Thought Content	☐
☐ 12. Bizarre Behavior	☐ 24. Mannerisms and Posturing

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

27308

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

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

☐ Not Done

BRIEF PSYCHIATRIC RATING SCALE (BPRS)

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

25233

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

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

☐ 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 surgicially 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 990101 - ____ (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

☐ Not Done

CHEMISTRIES

Study Day:
- ○ Pre-Intake Screening
- ○ Intake Screening
- ○ 6
- ○ 13 (Session 8)
- ○ 17 (Discharge)
- ○ 31 (Follow-up)
- ○ Unscheduled

Test Date ____ / ____ / 20____ (mm / dd / yyyy)

INSTRUCTIONS: Lab data can be transcribed either by using standard quanitity and unit listed at left, **OR** by using other quantitiy 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)	___	mEq/L*	____.____					
Potassium (K)	___.__	mEq/L*	____.____					
Chloride (Cl)	___	mEq/L*	____.____					
(CO_2)	___	mEq/L*	____.____					
Glucose	___	mg/dL	____.____					
Creatinine	__.__	mg/dL	____.____					
SGOT/AST	____	U/L	____.____					
SGPT/ALT	____	U/L	____.____					
GGT	____	U/L	____.____					
Total Bilirubin	___.__	mg/dL	____.____					
LDH	___	U/L	____.____					
CPK	____	U/L	____.____					
Alkaline phosphatase	___	U/L	____.____					
BUN	___	mg/dL	____.____					

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

Study Day: ⬭ -1 (Session 4) ⬭ 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

10072

Subject ID 990101 - ____ (site # / subject #)

Protocol # NIDA-CPU-ATOMOXETINE-0001

☐ 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

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): [ ][ ][ ]

13837

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 9 9 0 1 0 1 - [ ] [ ] [ ] [ ] (site # / subject #) Protocol # NIDA-CPU-ATOMOXETINE-0001

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

Study Day: ○ -6 (Session 1 & 2)

Schd Time: ○ -70 min pre ○ -56 min pre ○ -20 min pre ○ 4 min post ○ 40 min post ○ 64 min post ○ 100 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
1. Increased QRS Voltage	○	○
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:	○	○

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

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

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

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

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

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

National Institute on Drug Abuse

62370

Atomoxetine-Cocaine Interaction Study

Subject ID 9 9 0 1 0 1 - [ ] [ ] [ ] [ ] (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)

Schd Time: ○ -10 min pre ○ 4 min post ○ 40 min post ○ 64 min post ○ 100 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
1. Increased QRS Voltage	○	○
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:	○	○

[ ]

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

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

E. QRS (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)

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:

	abnormal	abnormal significant
1. Increased QRS Voltage	○	○
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:		

C. Ventricular rate (bpm): ___

D. PR (ms): ___

E. QRS (ms): ___

F. RR (ms): ___

G. QT (ms): ___

Completed by (initials): ___

5032

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - ____ (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

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)

4Did the subject receive all protocol defined study treatments?

○ Yes ○ No Last date of study drug treatment __ / __ / 20__ mm / dd / yyyy

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

○ Yes ○ No Follow-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 anotherr 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 990101 - [ ][ ][ ][ ] (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

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 [ ][ ] / [ ][ ] / 20[ ][ ]
mm / dd / yyyy

39818

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - ____ (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

☐ Not Done

HEMATOLOGY

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

Test Date ____ / ____ / 20____ (mm / dd / yyyy)

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

CBC	**Quantity**	**Unit**	**OR** **Other Quantity**	**Other Unit (specify)**	normal	abnormal	abnormal significant	not done
Hemoglobin	__.__	g/dL	_____.____		○	○	○	○
Hematocrit	__.__	%	_____.____		○	○	○	○
RBC	__.__	million/uL	_____.____		○	○	○	○
Platelet count	___	thousand/uL	_____.____		○	○	○	○
WBC	__.__	thousand/uL	_____.____		○	○	○	○
MCV	__.__	fL (mcm^3)	_____.____		○	○	○	○
Differential								
Neutrophils	__.__	%	_____.____		○	○	○	○
Lymphocytes	__.__	%	_____.____		○	○	○	○
Monocytes	__.__	%	_____.____		○	○	○	○
Eosinophils	__.__	%	_____.____		○	○	○	○
Basophils	__.__	%	_____.____		○	○	○	○

Provide comments for any abnormal value(s):

Completed by (initials): ___

28934

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

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

☐ 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 990101 - ____ (site # / subject #)

Protocol # 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	○	○	○	○	○	
Hepatitis B surface antibody result	○	○	○	○	○	
Hepatitis B core antibody result	○	○	○	○	○	
Hepatitis C virus antibody result	○	○	○	○	○	

Completed by (initials): ____

35180

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

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

☐ 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 entereing 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 be 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, inlcuding 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

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

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

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 9past 2 years) treatment with inhalded 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 pyhsiologically dependent on alcohol requiring medical detoxification. ○ yes ○ no

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

43384

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - ____ (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

☐ 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 __:__

Saline Infusion Stop Time __:__

Administered By: ___

-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	__:__	___ / ___	___

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - ____ (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

SCREENING INFUSION MONITORING

SESSION 1

20 mg Infusion Start Time __:__

20 mg Infusion Stop Time __:__

Administered By: ___

+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	__:__	___ / ___	___

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - ____ (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

SCREENING INFUSION MONITORING

SESSION 2

40 mg Infusion Start Time __:__

40 mg Infusion Stop Time __:__

Administered By: ___

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	__:__	___/___	___

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - [ ] [ ] [ ] [ ] **Protocol #** NIDA-CPU-ATOMOXETINE-0001

site # subject #

SCREENING 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): [ ][ ][ ]

46721

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - ____ (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

☐ Not Done

INFUSION MONITORING

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

Infusion Date: ____ / ____ / 20____ (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	__:__		
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	__:__	___ / ___	___

Administered By: ____

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - [ ][ ][ ][ ] **Protocol #** NIDA-CPU-ATOMOXETINE-0001

site # subject #

INFUSION MONITORING

2nd Infusion Start Time [ ][ ] : [ ][ ]

2nd Infusion Stop Time [ ][ ] : [ ][ ]

Administered By: [ ][ ][ ]

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	[ ][ ] : [ ][ ]	[ ][ ][ ] / [ ][ ][ ]	[ ][ ][ ]

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - ____ (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 ____ / ____ / 20____ 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	*Yes doesn't exclude	No history of disorder	Not evaluated	*If Yes, specify or describe
1. allergies: drug	○	○	○	○	
2. allergies: other, specify ____	○	○	○	○	
3. sensitivity to investigational agent or related compounds	○	○	○	○	
4. history of asthma	○	○	○	○	
5. head, ears, eyes, nose, throat (HEENT)	○	○	○	○	
6. cardiovascular	○	○	○	○	
7. renal	○	○	○	○	
8. hepatic	○	○	○	○	
9. pulmonary	○	○	○	○	
10. gastrointestinal	○	○	○	○	
11. musculoskeletal	○	○	○	○	
12. neurologic	○	○	○	○	
13. psychiatric	○	○	○	○	
14. dermatologic	○	○	○	○	
15. metabolic	○	○	○	○	
16. hematologic	○	○	○	○	

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - [ ][ ][ ][ ] (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

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 excludes	No 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

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - ____ (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-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)	○	○	○	○	
Head and neck	○	○	○	○	
Eyes, ears, nose/throat	○	○	○	○	
Cardiovascular	○	○	○	○	
Chest	○	○	○	○	
Lungs	○	○	○	○	
Abdomen (include liver/spleen)	○	○	○	○	
Extremities	○	○	○	○	
Skin, hair, nails	○	○	○	○	
Neuropsychiatric mental status	○	○	○	○	
Neuropsychiatric sensory/motor	○	○	○	○	
Musculoskeletal	○	○	○	○	
General appearance	○	○	○	○	
Other (specify) ____	○	○	○		
Other (specify) ____	○	○	○		

Completed by (initials): ____

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

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - ____ (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

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): ☐☐☐

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)

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

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - [ ][ ][ ][ ] (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-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 - [ ] [ ] [ ] [ ] **Protocol #** NIDA-CPU-ATOMOXETINE-0001

site # subject #

☐ 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

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - [ ][ ][ ][ ] **Protocol #** NIDA-CPU-ATOMOXETINE-0001

site # subject #

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

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - ____ (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

☐ 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 __ / __ / 20__ mm / dd / yyyy

SAE resolution date* __ / __ / 20__ mm / dd / yyyy

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - [ ] [ ] [ ] [ ] **Protocol #** NIDA-CPU-ATOMOXETINE-0001

site # subject #

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 inpairment/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/Resoved with sequelae
- ○ Fatal, date of death [ ][ ] / [ ][ ] / [ ][ ][ ][ ] mm / dd / yyyy

National Institute on Drug Abuse

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Subject ID 990101 - ____ (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

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 __ / __ / 20__

Investigational Agent Dose

Investigational Agent Unit

Investigational Agent Frequency

Investigational Agent Route

Investigational Agent Start Date __ / __ / 20__

Investigational Agent Stop Date __ / __ / 20__

OTHER ACTION TAKEN

Action taken for informed consent

- ○ None
- ○ Changed consent form
- ○ Unknown

Action taken for protocol

- ○ None
- ○ Changed protocol
- ○ Unknown

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

Subject ID 990101 - ____ (site # / subject #) **Protocol #** NIDA-CPU-ATOMOXETINE-0001

SERIOUS ADVERSE EVENT

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.)

Additional Comments

EVENT REPORTING

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:
(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 - [ ] [ ] [ ] [ ] **Protocol #** NIDA-CPU-ATOMOXETINE-0001

site # subject #

☐ 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 - [ ][ ][ ][ ] **Protocol #** NIDA-CPU-ATOMOXETINE-0001

site # subject #

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	○ no	Day 15	○ yes	○ no	Day 29	○ yes	○ no
Day 2	○ yes	○ no	Day 16	○ yes	○ no	Day 30 (yesterday)	○ yes	○ no
	○	○		○	○			
Day 4	○ yes	○ no	Day 18	○ yes	○ no			
	○	○		○	○			
Day 6	○ yes	○ no	Day 20	○ yes	○ no			
	○	○		○	○			
Day 8	○ yes	○ no	Day 22	○ yes	○ no			
	○	○		○	○			
Day 10	○ yes	○ no	Day 24	○ yes	○ no			
	○	○		○	○			
Day 12	○ yes	○ no	Day 26	○ yes	○ no			
	○	○		○	○			
Day 14	○ yes	○ no	Day 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	○	○	○	○	○	○	○	○	○	○	
Protein	○	○	○	○	○	○	○	○	○	○	
Glucose	○	○	○	○	○	○	○	○	○	○	
Ketones	○	○	○	○	○	○	○	○	○	○	
Leukocytes	○	○	○	○	○	○	○	○	○	○	
Nitrite	○	○	○	○	○	○	○	○	○	○	

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? ⬭ Yes ⬭ No ⬭ Unknown
(96.4 ≥ T ≤ 100.4 °F)

	Positive	Negative	Not done
Amphetamines	⬭	⬭	⬭
Barbiturates	⬭	⬭	⬭
Benzodiazepines	⬭	⬭	⬭
Cannabinoids (THC)	⬭	⬭	⬭
Cocaine metabolites	⬭	⬭	⬭
Methadone	⬭	⬭	⬭
Methamphetamine	⬭	⬭	⬭
Methaqualone	⬭	⬭	⬭
Opiates	⬭	⬭	⬭
Phencyclidine (PCP)	⬭	⬭	⬭
Propoxyphene	⬭	⬭	⬭

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? ○ Yes ○ No ○ Unknown
(96.4 ≥ T ≤ 100.4 °F)

	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 - ____ (site # / subject #)

Protocol # NIDA-CPU-ATOMOXETINE-0001

☐ 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)	__:__											
	__:__											
saline infusion)												
	__:__											
saline infusion)												
	__:__											
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 990101 - ____ (site # / subject #)

Protocol # NIDA-CPU-ATOMOXETINE-0001

☐ Not Done

VISUAL ANALOG SCALE(VAS)

Study Day:
- ○ -2 (Session 3)
- ○ -1 (Session 4)
- ○ 7 (Session 5)
- ○ 8 (Session 6)
- ○ 12 (Session 7)
- ● 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	__:__											
1st Infusion												
5 min	__:__											
15 min	__:__											
25 min	__:__											
35 min	__:__											

National Institute on Drug Abuse

Atomoxetine-Cocaine Interaction Study

26843

Subject ID 990101 - ____ (site # / subject #)

Protocol # NIDA-CPU-ATOMOXETINE-0001

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 - ____ (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.

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 - [ ][ ][ ][ ] **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.

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 done

Blood pressure- sitting (systolic / diastolic) [ ][ ][ ] / [ ][ ][ ] mm Hg ☐ Not done

Pulse rate-sitting [ ][ ][ ] beats/minute ☐ Not done

Comments:

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