NIDA – Annotated eCRF

NIDA-CPU-Methylphenidate-0001

DOUBLE-BLIND, PLACEBO-CONTROLLED ASSESSMENT OF POTENTIAL INTERACTIONS BETWEEN INTRAVENOUS METHAMPHETAMINE AND OSMOTIC-RELEASE METHYLPHENIDATE (OROS-MPH)

Add Subject Screen

Add New Subject	
Subject	
Center No:*	1 - Test Center ▼
	Add Subject

Visit Structure

Visit Name	Short Name
V01 OutPtScrn	

Project Structure

V01 OutPtScrn

Demographics/Informed Consent
ECG
Height and Weight
Vital Signs
Clinical Laboratory
Pregnancy Test
Urine Drug Screen

V02 InPtScrn

Methamphetamine Use History
Medical/Psychiatric History
Medical/Psychiatric History Details
Physical Examination
Physical Examination Details
Vital Signs
Pregnancy Test
Urine Drug Screen
Inclusion and Exclusion

V03 Day M3

ECG
Vital Signs
Urine Drug Screen
Saline/Methamphetamine Administration 1

V04 Day M2

ECG
Vital Signs
Urine Drug Screen
Saline/Methamphetamine Administration 2
Methamphetamine PK

V05 Day M1

Vital Signs
Urine Drug Screen
Methamphetamine PK

V06 Day 1

Vital Signs
Pregnancy Test
Urine Drug Screen
Randomization
Methamphetamine PK
OROS-MPH/Placebo Administration

V07 Day 2

Vital Signs
Clinical Laboratory
Urine Drug Screen
OROS-MPH/Placebo Administration
OROS-MPH/Placebo Blood Levels

V08 Day 3

Vital Signs
Urine Drug Screen
OROS-MPH/Placebo Administration

V09 Day 4

Vital Signs
Urine Drug Screen
OROS-MPH/Placebo Administration
OROS-MPH/Placebo Blood Levels

V10 Day 5

Vital Signs
Urine Drug Screen
OROS-MPH/Placebo Administration

V11 Day 6

Vital Signs
Urine Drug Screen
OROS-MPH/Placebo Administration
OROS-MPH/Placebo Blood Levels

V12 Day 7

ECG
Vital Signs
Urine Drug Screen
Saline/Methamphetamine Administration 1
OROS-MPH/Placebo Administration
OROS-MPH/Placebo Blood Levels

V13 Day 8

ECG
Vital Signs
Urine Drug Screen
Saline/Methamphetamine Administration 2
Methamphetamine PK
OROS-MPH/Placebo Administration
OROS-MPH/Placebo Blood Levels

V14 Day 9

Vital Signs
Urine Drug Screen
Methamphetamine PK
OROS-MPH/Placebo Administration

V15 Day 10

ECG
Height and Weight
Vital Signs
Clinical Laboratory
Pregnancy Test

Urine Drug Screen
Methamphetamine PK

V16 Follow Up Visit 1

Height and Weight

V17 Follow Up Visit 2

Height and Weight
Pregnancy Test

V18 Unscheduled

ECG
Physical Examination
Physical Examination Details
Height and Weight
Vital Signs
Clinical Laboratory
Pregnancy Test
Urine Drug Screen
Saline/Methamphetamine Administration 1
Saline/Methamphetamine Administration 2
OROS-MPH/Placebo Administration

V19 Study Level Forms

Adverse Events
Prior/Concomitant Medication
Subject Status Form

Form: DEMOGRAPHICS/INFORMED CONSENT *(Single form) Applicable to OutPtScrn visit.*

DEMOGRAPHICS/INFORMED CONSENT

1. Date of Visit ✳ *(DMDT / NUM - MM/DD/YY10.)*

   Date: [Pick a Month   ▼] / [Pick a Date...   ▼] / [Pick a Year   ▼]

2. Gender ✳ *(SEX / NUM)* ☐ Male *(=1)* ☐ Female *(=2)*

3. Age ✳ *(AGE / NUM)*

   [   ]

   Age > 45 or Age < 18 then message :
   ===> Age must be between 18 - 45, please verify.

4. Does subject qualify for study participation based on protocol I/E criterion (criteria) ? ✳ *(QUALIF / NUM)*

   ☐ Yes *(=1)* ☐ No *(=0)*

   4.1 If No, did sponsor authorize enrolment? ✳ *(QUALAUT / NUM)*

   ☐ Yes *(=1)* ☐ No *(=0)*

   4.2 Failed Inclusion Criterion Number(s) (#1 - #12) *(QUALF1 / NUM)*

   [   ]

   4.3 Failed Inclusion Criterion Number(s) (#1 - #12) *(QUALF2 / NUM)*

   [   ]

   4.4 Failed Inclusion Criterion Number(s) (#1 - #12) *(QUALF3 / NUM)*

   [   ]

   4.5 Failed Inclusion Criterion Number(s) (#1 - #12) *(QUALF4 / NUM)*

   [   ]

   4.6 Failed Inclusion Criterion Number(s) (#1 - #12) *(QUALF5 / NUM)*

   [   ]

   4.7 Failed Exclusion Criterion Number(s) (#1 - #20) *(QUALF6 / NUM)*

   [   ]

   4.8 Failed Exclusion Criterion Number(s) (#1 - #20) *(QUALF7 / NUM)*

   [   ]

   4.9 Failed Exclusion Criterion Number(s) (#1 - #20) *(QUALF8 / NUM)*

   [   ]

   4.10 Failed Exclusion Criterion Number(s) (#1 - #20) *(QUALF9 / NUM)*

   [   ]

   4.11 Failed Exclusion Criterion Number(s) (#1 - #20) *(QUALF10 / NUM)*

   [   ]

5. Did subject provide written and signed Informed Consent? ✳ *(CONSENT / NUM)*

⬜ Yes *(=1)*   ⬜ No *(=0)*

5.1 Date of Informed Consent ✳ *(ICDT / NUM - MM/DD/YY10.)*

Date: | Pick a Month ▼ | / | Pick a Date... ▼ | / | Pick a Year ▼ |

6. Racial Designation ✳ *(RACE / NUM)*

White *(=1)*

Native or Inuit *(=2)*

Asian *(=3)*

Black or of African Descent *(=4)*

Hispanic or Latino *(=5)*

Native Hawaiian or other Pacific Islander *(=6)*

Other *(=7)*

6.1 Other race, specify ✳ *(RACESP / CHAR)*

Form: METHAMPHETAMINE USE HISTORY *(Single form) Applicable to InPtScrn visit.*

METHAMPHETAMINE USE HISTORY

Methamphetamine Use History

⁑

☐   ☐

2. Number of times used in the past 6 weeks ⁑*(METHNUM / NUM)*

3. Date last used methamphetamine ⁑*(METHLDT / CHAR – MMM DD, YYYY)*

| Pick a Month ▼ | Pick a Date... ▼ | Pick a Year ▼ |

4. Has subject been diagnosed via DSM-IV with methamphetamine dependence or abuse? ⁑

☐   ☐

5. Has subject NOT been diagnosed with Axis I Disorders? ⁑*(METHDIAA / NUM)*

☐   ☐

Form: ECG *(Recurring form) Applicable to OutPtScrn, Day – 3, Day – 2, Day 7, Day 8, Day 10 and*

ECG

C   C
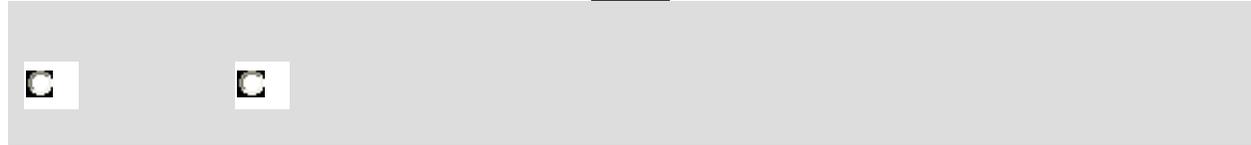
(QTc Interval > 450 or QTc Interval < 350) and Sex = Female
then message :
===>Question 11. QTc Interval should be between
350 and 450 ms for Female, please verify.

(QTc Interval > 440 or QTc Interval < 350) and Sex = Male
then message :
===>Question 11. QTc Interval should be between
350 and 440 ms for Male, please verify.

1. ECG Time Point   * *(ECGTYPE / NUM)*

| None selected ▾ |

- 15 min Infusion 1 *(=1)* + 30 min Infusion 1 *(=2)* + 90 min Infusion 1 (+ 30 min Infusion 2) *(=3)* +120 min Infusion 1 (+ 60 min Infusion 2) *(=4)* N/A *(=5)*

2. Date ECG Performed *(ECGDT / NUM - MM/DD/YY10.)*

Date: | Pick a Month ▾ | / | Pick a Date... ▾ | / | Pick a Year ▾ |

3. Actual Time ECG Performed   *(ECGTM / NUM – TIME18.)* ◄ *If ECG Status = Assessable or ECG Status = Not assessable, then informed miss.*

Time: | Hours ▾ | : | Minutes ▾ |

4. ECG Status   * *(ECGSTAT / NUM)*

5. Reason Not assessable/Not done   *
(ECGSTASP / CHAR)

| |

6. Ventricular Rate (bpm) ✳ *(VRATE / NUM)*

(Ventricular Rate > 100 or Ventricular Rate < 35) then message :
===>Question 6. Ventricular Rate should be between 35 and 100 bpm, please verify.

7. Sinus Rhythm Normal? ✳ *(RHYTHM / NUM)*

☐   ☐

✳   9. QRS Interval (ms) ✳ *(QRS / NUM)*

10. QT Interval (ms) ✳ *(QT / NUM)*   11. QTc Interval (ms) ✳ *(QTC / NUM)*

12. ECG Result   *(ECGRES / NUM)* ⟵ *If ECG Status = Assessable then informed miss.*

☐   Normal *(=1)*

☐

☐

13. If Abnormal (CS or NCS), please comment: ✳ *(ECGABSP1 / CHAR)*

14. If Abnormal (CS or NCS), please comment (continued):
(ECGABSP2 / CHAR)

MEDICAL/PSYCHIATRIC HISTORY

Date of Medical/Psychiatric History * *(MHDT / NUM - MM/DD/YY10.)*

Date: | Pick a Month ▾ | / | Pick a Date... ▾ | / | Pick a Year ▾ |

Are there any findings for the following body systems?

Body System Number *(MYSYS01 / NUM)*	1. Eyes, Ears, Nose & Throat * *(MHRES01 / NUM)*

Body System Number *(MHSYS02 / NUM)*	2. Pulmonary/Respiratory * *(MHRES02 / NUM)*

Body System Number *(MHSYS03 / NUM)*	3. Cardiovascular * *(MHRES03 / NUM)*

Body System Number *(MHSYS04 / NUM)*	4. Gastrointestinal * *(MHRES04 / NUM)*

Body System Number *(MHSYS05 / NUM)*	5. Reproductive/Breast * *(MHRES05 / NUM)*

Body System Number *(MHSYS06 / NUM)*	6. Urologic/Renal ✳ *(MHRES06 / NUM)*
Body System Number *(MHSYS07/ NUM)*	7. Hepatic/Biliary ✳ *(MHRES07 / NUM)*
Body System Number *(MHSYS08 / NUM)*	8. Musculoskeletal ✳ *(MHRES08 / NUM)*
Body System Number *(MHSYS09 / NUM)*	9. Neurologic ✳ *(MHRES09 / NUM)*
Body System Number *(MHSYS10 / NUM)*	10. Endocrine/Metabolic ✳ *(MHRES10 / NUM)*
Body System Number *(MHSYS11 / NUM)*	11. Hematologic/Lymphatic ✳ *(MHRES11 / NUM)*

Body System Number   *(MHSYS12 / NUM)*

12. Dermatologic * *(MHRES12 / NUM)*

Body System Number   *(MHSYS13 / NUM)*

13. Psychiatric * *(MHRES13 / NUM)*

13.1   If Psychiatric, did subject have any of the following Axis I disorders: psychosis, bipolar I disorder, organic brain disease, dementia, major depression, schizoaffective disorder, schizophrenia, anorexia nervosa, or bulimia disorder? * *(SCODEPS / NUM)*

⊙ Yes *(=1)*   ⊙ No *(=0)*

Body System Number   *(MHSYS14 / NUM)*

14. Allergic/Immunologic * *(MHRES14 / NUM)*

Body System Number   *(MHSYS98 / NUM)*

15. Other * *(MHRES15 / NUM)*

15.1 If Yes, please specify: *
(SCODESP / CHAR)

If "Yes" is selected for any body system finding, then display comment:

If "Not Done" then describe: ✼	If "Not Done" then describe (continued):

MEDICAL/PSYCHIATRIC HISTORY DETAILS

Date: | Pick a Month ▾ | / | Pick a Date... ▾ | / | Pick a Year ▾ |

Body System ✳ *(SCODE / NUM)*

1. Abnormality Number ✳ *(MHABNUM / NUM)*

2. MD's Assessment ✳ *(MDASMT / NUM)*

3. Condition/Diagnosis/Surgery ✳ *(MHDESC / CHAR)*

4. Onset Date ✳ *(MHSTDT / CHAR – MMM DD, YYYY)*

| Pick a Month ▼ | Pick a Date... ▼ | Pick a Year ▼ |

Onset Date > End Date then message :
===> Onset Date should not be later than End Date, please verify.

5. Ongoing? ✳ *(MHONGO / NUM)* ☐ Yes *(=1)* ☐ No *(=0)*

5.1 End Date ✳ *(MHENDT / CHAR – MMM DD, YYYY)*

| Pick a Month ▼ | Pick a Date... ▼ | Pick a Year ▼ |

Onset Date > End Date then message :
===> Onset Date should not be later than End Date, please verify.

Form: PHYSICAL EXAMINATION *(Single form) Applicable to InPtScrn and Unscheduled visit.*

PHYSICAL EXAMINATION

Date of Physical Exam ✳ *(PEDT / NUM - MM/DD/YY10.)*

Date: [Pick a Month ▼] / [Pick a Date... ▼] / [Pick a Year ▼]

Body System Number (PESYS01 / NUM)	✳ [▼]
Body System Number (PESYS02 / NUM)	2. Skin (PERES02 / NUM) [▼]
Body System Number (PESYS03 / NUM)	3. Head, Eyes. Ears, Nose, ✳ [▼]
Body System Number (PESYS04 / NUM)	4. Lungs ✳ (PERES04 / NUM) [▼]
Body System Number (PESYS05 / NUM)	5. Cardiovascular ✳ (PERES05 / NUM) [▼]

Body System Number *(PESYS06 / NUM)*	6. Abdomen (incl liver/spleen) ✳ *(PERES06 / NUM)*
Body System Number *(PESYS07/ NUM)*	7. Musculoskeletal/Extremities ✳ *(PERES07 / NUM)*
Body System Number *(PESYS08 / NUM)*	8. Sensory/Motor Status ✳ *(PERES08 / NUM)*
Body System Number *(PESYS09 / NUM)*	9. Neuropsychiatric mental status ✳ *(PERES09 / NUM)*
Body System Number *(PESYS10 / NUM)*	10. Other ✳ *(PERES10 / NUM)*

10.1 If Abnormal, please specify ✳
 (OTHERSP / CHAR))

If "Abnormal" is selected for any body system finding, then display comment:

If "Not Done" then describe: ✳	If "Not Done" then describe (continued):

Form: PHYSICAL EXAMINATION DETAILS *(Recurring form)* *Applicable to InPtScrn and Unscheduled visit.*

PHYSICAL EXAMINATION DETAILS

Date: | Pick a Month ▼ | / | Pick a Date... ▼ | / | Pick a Year ▼ |

Body System ✳ *(PESCODE / NUM)*

1. Abnormality Number ✳ *(PEABNUM / NUM)*

2. Abnormality Description ✳ *(PEAB / CHAR)*

3. Exam Result ✳ *(PEABRES / NUM)*

Form: HEIGHT AND WEIGHT *(Single form) Applicable to OutPtScrn, Day 10, Follow Up visit 1, Follow*

HEIGHT AND WEIGHT

1. Date of Height and Weight taken ✳ *(HTWTDT / NUM - MM/DD/YY10.)*

Date: [Pick a Month ▼] / [Pick a Date... ▼] / [Pick a Year ▼]

2. Height (cm) ✳ *(HT / NUM)*

[   ]

(Height > 215 or Height < 140) and Height ≠ 0 then message :

4. *Calculated BMI (kg/m^2)* *(BMIC / NUM)*

[   ]

3. Weight (kg) ✳ *(WT / NUM)*

[   ]

(Weight > 150 or Weight < 50) and Weight ≠ 0 then

Form: VITAL SIGNS *(Recurring form) Applicable to all visits except Follow Up visit 1, Follow Up visit 2 and*

VITAL SIGNS

1. Vitals type ✴ *(PREPOST / NUM)*

⊡   ⊡

(Visit = OutPtScrn or Visit = InPtScrn or Visit = Day-3 or Visit = Day-2 or Visit = Day-1) and Vitals type = Post-dose then message :
===> If visit is OutPtScrn or InPtScrn or Day M3 or Day M2 or Day M1, Vitals type should be Pre-dose, please verify.

(Visit = Follow Up visit 1 or Visit = Follow Up visit 2) and Vitals type = Pre-dose then message :
===> If visit is Follow-up visit 1 or Follow-up visit 2, Vitals type should be Post-dose, please verify.

2. Date Vitals Taken *(VSDT / NUM - MM/DD/YY10.)*

Date: | Pick a Month ▾ | / | Pick a Date... ▾ | / | Pick a Year ▾ |

3. Time Point Vitals to be taken ✴ *(VSTP / NUM)*

| None selected ▾ |

- Pre-infusion *(=1)*
- 25 min Infusion 1 *(=2)*
- 15 min Infusion 1 *(=3)*
+ 3 min Infusion 1 *(=4)*
+ 6 min Infusion 1 *(=5)*
+ 9 min Infusion 1 *(=6)*
+ 12 min Infusion 1 *(=7)*
+ 15 min Infusion 1 *(=8)*
+ 20 min Infusion 1 *(=9)*
+ 30 min Infusion 1 *(=10)*
+ 45 min Infusion 1 *(=11)*
+ 55 min Infusion 1 *(=12)*
+ 3 min Infusion 2 *(=13)*
+ 6 min Infusion 2 *(=14)*
+ 9 min Infusion 2 *(=15)*
+ 12 min Infusion 2 *(=16)*
+ 15 min Infusion 2 *(=17)*
+ 20 min Infusion 2 *(=18)*
+ 30 min Infusion 2 *(=19)*
+ 45 min Infusion 2 *(=20)*
+ 60 min Infusion 2 *(=21)*
+ 90 min Infusion 2 *(=22)*
+ 120 min Infusion 2 *(=23)*
+ 150 min Infusion 2 *(=24)*
+ 180 min Infusion 2 *(=25)*
+ 210 min Infusion 2 *(=26)*
+ 240 min Infusion 2 *(=27)*
+ 300 min Infusion 2 *(=28)*
+ 360 min Infusion 2 *(=29)*
+ 420 min Infusion 2 *(=30)*
+ 480 min Infusion 2 *(=31)*
+ 10 hr Infusion 2 *(=32)*
+ 12 hr Infusion 2 *(=33)*
+ 24 hr Infusion 2 *(=34)*
+ 48 hr Infusion 2 *(=35)*
NA (=36)

4. Actual Time Vitals Taken * *(VSTM / NUM – TIME18.)*

   Time: [Hours ▼] : [Minutes ▼]

5. Status: Valid/Not Valid/Not Done * *(STATUS / NUM)*

   ☐ Valid *(=1)*

   ☐

   ☐

8. Arm (to be consistent throughout study) * *(ARM / NUM)*

   ☐   ☐   ☐

9. Systolic BP (mmHg) * *(SBP / NUM)*

10. Diastolic BP (mmHg) * *(DBP / NUM)*

11. Heart Rate (beats/min) * *(HR / NUM)*

12. Respiration Rate (breaths/min) * *(RR / NUM)*

13. Oral Temperature (C) * *(TEMP / NUM)*

Form: CLINICAL LABORATORY *(Recurring form) Applicable to OutPtScrn visit, Day 2, Day 10 and*

CLINICAL LABORATORY

1. Date Sample Collected ✷ *(LBDT / NUM - MM/DD/YY10.)*

Date: [Pick a Month ▼] / [Pick a Date... ▼] / [Pick a Year ▼]

2. Time Sample Collected ✷ *(LBTM / NUM – TIME18.)*

Time: [Hours ▼] : [Minutes ▼]

	Yes *(=1)*	
3. Hematology done? ✷ *(HEMA / NUM)*	⊙	⊙
✷	⊙	⊙
✷	⊙	⊙
✷	⊙	⊙

Question 7 is only applicable to OutPtScrn, InPtScrn and Unscheduled visit :

7. HIV Test Informed Consent given? ✷*(HIVIC / NUM)*

⊙ Yes *(=1)* ⊙ No *(=0)*

> 7.1 Date HIV Test consent given ✷*(HIVICDT / NUM - MM/DD/YY10.)*
>
> Date: [Pick a Month ▼] / [Pick a Date... ▼] / [Pick a Year ▼]
>
> 7.2 HIV Test done? ✷*(HIV / NUM)*
>
> ⊙ Yes *(=1)* ⊙ No *(=0)*

Form: PREGNANCY TEST *(Single form) Applicable to OutPtScrn, InPtScrn, Day 1, Day 10, Follow Up*

PREGNANCY TEST

ReadOnly field - Gender (Propagated from DEMOGRAPHICS/INFORMED CONSENT form)

1. Date of Pregnancy Test ✳ *(PRGDT / NUM - MM/DD/YY10.)*

    Date: [Pick a Month ▼] / [Pick a Date... ▼] / [Pick a Year ▼]

2. Type of test ✳ *(PRGTYPE / NUM)* ☐ Urine *(=1)* ☐ Serum *(=2)*

    Type of test = Serum and Visit is not equal to OutPtScrn then message :
    ===> Type of test should be "Urine" for any visits other than OutPtScrn visit, please verify.

    Type of test = Urine and Visit = OutPtScrn then message :
    ===> Type of test should be "Serum" for OutPtScrn visit, please verify.

3. Result ✳ *(PRGRES / NUM)*

    Positive *(=1)*

    Negative *(=2)*

    Not Applicable (Male) *(=3)*

    Not Done *(=4)*

Gender = Male and (Result = Positive or Result = Negative) then message :
===> Subject is Male, therefore, answer to "Result" should not be "Positive or Negative", please verify.

Gender = Female and Result = Not Applicable (Male) then message :
===> Subject is Female, therefore, answer to "Result" should not be "Not Applicable (Male)", please verify.

4. If pregnancy test is marked "Not Done", comment: ✳*(PRGRESP1 / CHAR)*

    [   ]

5. If pregnancy test is marked "Not Done", comment (continued): *(PRGRESP2 / CHAR)*

    [   ]

Form: URINE DRUG SCREEN *(Single form) Applicable to all visits except Follow Up visit 1, Follow Up*

URINE DRUG SCREEN

1. Date of UDS ✳ *(UDSDT / NUM - MM/DD/YY10.)*

Date: | Pick a Month ▾ | / | Pick a Date... ▾ | / | Pick a Year ▾ |

2. Time of UDS ✳ *(UDSTM / NUM – TIME18.)*

Time: | Hours ▾ | : | Minutes ▾ |

Time of UDS > 10:00am or Time of UDS < 6:00am then message :
===> UDS should be performed around 8:00am (between 6:00am and 10:00am) each day, please verify.

	Positive *(=1)*		
3. (Cocaine) COC ✳ *(UDSCOC / NUM)*	◖	◖	◖
✳	◖	◖	◖
✳	◖	◖	◖
✳	◖	◖	◖

7. Comments on UDS   *(UDSSP1 / CHAR)*

Form: INCLUSION/EXCLUSION *(Single form) Applicable to InPtScrn visit.*

INCLUSION/EXCLUSION

ReadOnly field - Gender (Propagated from DEMOGRAPHICS/INFORMED CONSENT form)

C

Sex = Male and (Inclusion criteria 12 = Yes or Inclusion criteria 12 = No) then message:
===> Subject is Male, therefore, answer to Inclusion Criteria #12 should not be "Yes" or "No", please verify.

Sex = Female and (Inclusion criteria 12 = N/A) then message:
===> Subject is Female, therefore, answer to Inclusion Criteria #12 should not be "N/A", please verify.

Sex = Male and (Exclusion criteria 13 = Yes or Exclusion criteria 13 = No) then message:
===> Subject is Male, therefore, answer to Exclusion Criteria #13 should not be "Yes" or "No", please verify.

Sex = Female and (Exclusion criteria 13 = N/A) then message:
===> Subject is Female, therefore, answer to Exclusion Criteria #13 should not be "N/A", please verify.

Inclusion Criteria	Yes		
1. Be volunteers who meet DSM-IV criteria for methamphetamine abuse or ✳	C	C	
✳	C	C	
✳	C	C	
✳	C	C	
✳	C	C	
✳	C	C	
✳	C	C	

than three times the upper limit of normal. ✳ *(INC08 / NUM)*	○	○	
✳	○	○	
✳	○	○	
✳	○	○	
✳	○	○	○

Inclusion 12 continued : Birth control must be in effect starting at least 7 days (14 days for hormone-based methods used alone) prior to clinic intake, and should extend at least until the last follow-up visit.
 a. oral contraceptives
 b. contraceptive sponge or patch
 c. barrier (diaphragm or condom) with spermicide
 d. intrauterine progesterone, or non-hormonal contraceptive system
 e. levonorgestrel implant
 f. medroxyprogesterone acetate contraceptive injection
 g. complete abstinence from sexual intercourse

Exclusion Criteria	Yes		
1. Have a current or past history of seizure disorder, including alcohol-or stimulant- ✳	○	○	
✳	○	○	
✳	○	○	
✳	○	○	
✳	○	○	

these symptoms. * *(EXC06 / NUM)*	⊙	⊙
*	⊙	⊙
*	⊙	⊙
*	⊙	⊙
*	⊙	⊙
*	⊙	⊙
*	⊙	⊙

*	⊙	⊙	⊙
14. Have a significant family history of early cardiovascular morbidity or mortality in *	⊙	⊙	
*	⊙	⊙	

note). * *(EXC16 / NUM)*	○	○
*	○	○
*	○	○
*	○	○
*	○	○

Form: RANDOMIZATION *(Single form) Applicable to Day 1.*

RANDOMIZATION

1. Date of Randomization ✳ *(RANDDT / NUM - MM/DD/YY10.)*

   Date: | Pick a Month ▼ | / | Pick a Date... ▼ | / | Pick a Year ▼ |

2. Randomization Number ✳ *(RANDNO / NUM)*

   [   ]

Form: SALINE/METHAMPHETAMINE ADMINISTRATION 1 *(Single form) Applicable to Day – 3, Day 7*

SALINE/METHAMPHETAMINE ADMINISTRATION 1

| Pick a Month ▼ | Pick a Date... ▼ | Pick a Year ▼ |

Date last used methamphetamine is not 3 days earlier than Infusion 1 Date then message :
===> Date last used methamphetamine should be at least 3 days prior to Day -3, please verify.

Infusion (Day -3 and Day 7) 15 mg

✳

Date: | Pick a Month ▼ | / | Pick a Date... ▼ | / | Pick a Year ▼ |

2. Saline Start Time ✳   3. Methamphetamine Start Time ✳

Time: | Hours ▼ | : | Minutes ▼ | Time: | Hours ▼ | : | Minutes ▼ |

Methamphetamine Start Time is not 1 hour after Saline Start Time then message :
===> Methamphetamine Start Time should be at least 1 hour after Saline Start Time, please verify.

4. Did subject complete the 15 mg Methamphetamine infusion? ✳   *(MA1COMP / NUM)*

   ⊙   ⊙

5. If 'No', specify reason and record any AEs on the AE form ✳ *(MA1REAS / CHAR)*

   [   ]

Infusion Comments

[   ]

7. Comments (continued)   *(MA1COM2 / CHAR)*

[   ]

Form: SALINE/METHAMPHETAMINE ADMINISTRATION 2 *(Single form) Applicable to Day – 2, Day 8*

SALINE/METHAMPHETAMINE ADMINISTRATION 2

Infusion (Day -2 and Day 8) 30 mg

Date: | Pick a Month ▼ | / | Pick a Date... ▼ | / | Pick a Year ▼ |

2. Saline Start Time

Time: | Hours ▼ | : | Minutes ▼ |

3. Methamphetamine Start Time

Time: | Hours ▼ | : | Minutes ▼ |

Methamphetamine Start Time is not 1 hour after Saline Start Time then message :
===> Methamphetamine Start Time should be at least 1 hour after Saline Start Time, please verify.

4. Did subject complete the 30 mg Methamphetamine infusion? *(MA2COMP / NUM)*

○   ○

5. If 'No', specify reason and record any AEs on the AE form *(MA2REAS / CHAR)*

[   ]

Infusion Comments

[   ]

7. Comments (continued)   *(MA2COM2 / CHAR)*

[   ]

Form: METHAMPHETAMINE PK *(Recurring form) Applicable to Day – 2, Day – 1, Day 1, Day 8, Day 9*

METHAMPHETAMINE PK

Date Sample Collected   *(MAPKDT / NUM - MM/DD/YY10.)*

Date: | Pick a Month ▼ | / | Pick a Date... ▼ | / | Pick a Year ▼ |

1. Time Point ✻ *(MAPKTP / NUM)*

| None selected ▼ |

2. Actual Time Sample Collected ✻ *(MAPKTM / NUM – TIME18.)*

Time: | Hours | : | Minutes |

3. PK Sample Status ✻ *(MAPKSTAT / NUM)*

☐ Usable *(=1)*

☐

☐

3.1 Reason Not Usable/Not Done ✻
(MAPKSP1 / CHAR)

3.2 Reason Not Usable/Not Done
(continued) *(MAPKSP2 / CHAR)*

Form: OROS-MPH/PLACEBO ADMINISTRATION *(Single form) Applicable to Day 1, Day 2, Day 3,*

OROS-MPH/PLACEBO ADMINISTRATION

1. Dosing Date ***** *(DADT / NUM - MM/DD/YY10.)*

   Date: | Pick a Month ▼ | / | Pick a Date... ▼ | / | Pick a Year ▼ |

2. Dosing Time ***** *(DASTTM / NUM – TIME18.)*

   Time: | Hours ▼ | : | Minutes ▼ |

If visit = Day 1 or visit = Day 2 then display header :

3. Dosing Comments   *(DACOM1 / CHAR)*

4. Comments (continued)   *(DACOM2 / CHAR)*

Form: OROS-MPH/PLACEBO BLOOD LEVELS *(Recurring form) Applicable to Day 2, Day 4, Day 6,*

OROS-MPH/PLACEBO BLOOD LEVELS

Date Sample Collected   *(DAPKDT / NUM - MM/DD/YY10.)*

Date: | Pick a Month ▾ | / | Pick a Date... ▾ | / | Pick a Year ▾ |

1. Time Point ✳ *(DAPKTP / NUM)*

| None selected ▾ |

2. Actual Time Sample Collected ✳ *(DAPKTM / NUM – TIME18.)*

Time: | Hours ▾ | : | Minutes ▾ |

3. Sample Status ✳ *(DAPKSTAT / NUM)*

  ○ Usable *(=1)*

  ○

  ○

3.1 Reason Not Usable/Not Done ✳
(DAPKSP1 / CHAR)

3.2 Reason Not Usable/Not Done
(continued) *(DAPKSP2 / CHAR)*

Form: ADVERSE EVENTS *(Recurring form) Applicable to Study Level Forms.*

ADVERSE EVENTS

1. AE Type ✳ *(AETYPE / NUM)*

  C   C

3. Adverse Event Description/Sign/Symptom (diagnosis where possible) ✳ *(DESC / CHAR)*

4. Date of Onset ✳ *(AESTDT / CHAR – MMM DD, YYYY)*	5. Onset Time ✳ *(AESTTM / CHAR)*
Pick a Month Pick a Date... Pick a Year	Hours : Minutes
6. End Date ✳ *(AEENDT / CHAR – MMM DD, YYYY)*	7. End Time ✳ *(AEENTM / CHAR)*
Pick a Month Pick a Date... Pick a Year	Hours : Minutes

Date of Onset > End Date then message :
===> Date of Onset should not be later than End date, please verify.

Onset Time > End Time and Date of Onset = End Date then message :
===> Onset time should not be later than End time, please verify.

8. Severity ✳ *(AESEV / NUM)*	9. Frequency ✳ *(AEFREQ / NUM)*
10. Any action taken for AE? ✳ *(AEACTION / NUM)*	

10.1 Action taken for AE ✳

      Non-Drug Therapy given (record in Notes section below) *(NONDRUG / NUM)*

      New medication given (record in Notes section below AND in ConMeds form) *(DRUGTX / NUM)*

  (TRUE=1, FALSE=0)

11. Was the subject withdrawn from the study due to this AE? ⚹ *(WDAE / NUM)*

☐   ☐

12. AE Outcome ⚹ *(OUTCOME / NUM)*

12.1 Unresolved Status ⚹ *(UNRES / NUM)*

    Ongoing *(=1)*
☐   Stabilized *(=2)*
☐   To be seen by own physician *(=3)*
☐   To be referred for specialist follow-up *(=4)*
☐   Lost to follow-up *(=5)*
☐   Other *(=6)*

12.1.1 Please specify Other ⚹ *(UNRESSP / CHAR)*

[   ]

13. Serious Adverse Event? ⚹ *(SAE / NUM)*

☐

⚹

[   ]

16. Notes (continued)   *(AENOTE2 / CHAR)*

17. Notes (continued)   *(AENOTE3 / CHAR)*

18. Notes (continued)   *(AENOTE4 / CHAR)*

Form: PRIOR/CONCOMITANT MEDICATION *(Recurring form)   Applicable to Study Level Forms.*

PRIOR/CONCOMITANT MEDICATION

2. Medication Number ＊ *(CMEDNO / NUM)*

3. Medication Name ＊ *(CMED / CHAR)*

4. Dose ＊ *(CMDOSE / CHAR)*   5. Unit ＊ *(CMUNIT / CHAR)*

6. Route ＊ *(CMROUTE / CHAR)*   7. Frequency ＊ *(CMFREQ / CHAR)*

8. ConMed Started Pre-dosing? ＊ *(PRETX / NUM)*

    ☐ Yes *(=1)*   ☐ No *(=0)*

9. Start Date ＊ *(CMSTDT / CHAR – MMM DD, YYYY)*   10. Start Time ＊ *(CMSTTM / CHAR)*

| Pick a Month ▼ | Pick a Date... ▼ | Pick a Year ▼ | | Hours ▼ | : | Minutes ▼ |

*Start Date > Stop Date then message :
===> Start Date should not be later than Stop Date,
please verify.*

*Start Time > Stop Time and Start Date = Stop
Date then message :
===> Start Time should not be later than Stop
Time, please verify.*

11. Ongoing at Follow Up Visit 2? ＊ *(POSTTX / NUM)*

    ☐ Yes *(=1)*   ☐ No *(=0)*

12. Stop Date ＊ *(CMENDT / CHAR – MMM DD, YYYY)*

| Pick a Month ▼ | Pick a Date... ▼ | Pick a Year ▼ |

13. Stop Time ＊ *(CMENTM / CHAR)*

| Hours ▼ | : | Minutes ▼ |

*Start Date > Stop Date then
message :
===> Start Date should not be
later than Stop Date, please
verify.*

*Start Time > Stop Time and Start
Date = Stop Date then message :
===> Start Time should not be
later than Stop Time, please
verify.*

14. Indication ✳ *(INDICAT / CHAR)*

15. Was ConMed administered for an Adverse Event? ✳ *(AETX / NUM)*

 ☐ Yes *(=1)* ☐ No *(=0)*

16. AE Number ✳ *(CMAENUM / CHAR)*

Form: SUBJECT STATUS FORM *(Single form) Applicable to Study Level Forms.*

SUBJECT STATUS FORM

○ Yes *(=1)* ⟶ 1.1 Date of Completion ✳ *(TTDT / NUM - MM/DD/YY10.)*

Date: Pick a Month ▾ / Pick a Date... ▾ / Pick a Year ▾

○

1.2 Is this subject "evaluable" (did he/she receive all doses of OROS-MPH or placebo, had methamphetamine PK blood samples collected up to the 12-hour time point during infusion session #4, and receive the entire methamphetamine dose during infusion sessions #2 and #4)? *(TTEV / NUM)*

○ Yes *(=1)*   No *(=0)*

1.2.1 Date Evaluable ✳ *(EVDT / NUM - MM/DD/YY10.)*

Date: Pick a Month ▾ / Pick a Date... ▾ / Pick a Year ▾

1.2.2 Date of Early Withdrawal ✳ *(EWDT / NUM - MM/DD/YY10.)*

Date: Pick a Month ▾ / Pick a Date... ▾ / Pick a Year ▾

1.2.3 Reason for Early Withdrawal ✳ *(EWREAS / NUM)*

○ Pregnancy *(=1)*

○ Withdrawal of consent *(=2)*

○ Administrative reasons *(=3)*

○ Major protocol violation *(=4)*

○ It is in the best interest of the subject *(=5)*

○ Non compliance *(=6)*

○ AE or SAE *(=7)*

○ Met stopping criteria for further study participation *(=8)*

○ Lost to follow-up *(=9)*

○ Other reason *(=10)*

1.2.4 Detailed reason for Early Withdrawal ✳ *(EWSP1 / CHAR)*

[   ]

1.2.5 Detailed reason for Early Withdrawal (continued) *(EWSP2 / CHAR)*

[   ]

2. Was Randomization Code broken? ✳ *(CB / NUM)*
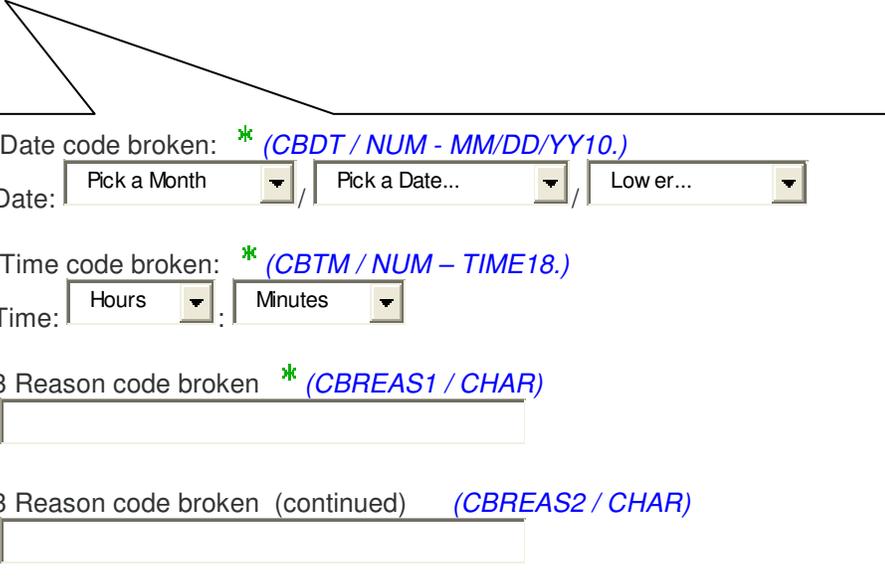
2.1 Date code broken: ✳ *(CBDT / NUM - MM/DD/YY10.)*

Date: | Pick a Month ▾ | / | Pick a Date... ▾ | / | Low er... ▾ |

2.2 Time code broken: ✳ *(CBTM / NUM – TIME18.)*

Time: | Hours ▾ | : | Minutes ▾ |

2.3 Reason code broken ✳ *(CBREAS1 / CHAR)*

2.3 Reason code broken (continued)   *(CBREAS2 / CHAR)*

OnSubmit event :

If answer to question 1 "Did the subject complete the entire study as per protocol (from Screening to Follow Up Visit 2)?" = Yes, set subject status as "Study Completed".

If answer to question 1 "Did the subject complete the entire study as per protocol (from Screening to Follow Up Visit 2)?" = No, set subject status as "Withdrawn".

SAS Export – Name of the Dataset

	Screen Name	Export name in SAS
1	Demographics/Informed Consent	DEMOGR1
	Methamphetamine Use History	METHAM2
	ECG	ECG3
	Medical/Psychiatric History	MEDICA21
	Medical/Psychiatric History Details	MEDICA22
	Physical Exam	PHYSIC23
	Physical Exam Details	PHYSIC24
	Height and Weight	HEIGHT6
	Vital Signs	VITALS7
	Clinical Laboratory	CLINIC8
	Pregnancy Test	PREGNA9
	Urine Drug Screen	URINED10
	Inclusion and Exclusion	INCLUS11
	Randomization	RANDOM12
	Saline/Methamphetamine Administration 1	SALINE17
	Saline/Methamphetamine Administration 2	SALINE20
	Methamphetamine PK	METHAM18
	OROS-MPH/Placebo Administration	OROSMP13
	OROS-MPH/Placebo Blood Levels	OROSMP14
	Adverse Events	ADVERS15
	Prior/Concomitant Medication	PRIORC16
	Subject Status Form	SUBJEC19