

Subject Number _____ Initials _____

MAPS Study MT1

CRF

Page 1

Demographics

Date of Screening _____ - _____ - _____
dd mmm yyyy (may start up to one month prior to enrollment)

Date of Birth: _____ - _____ - _____
dd mmm yyyy

Visit #1 Date of Enrollment _____ - _____ - _____
dd mmm yyyy

Sex: Male
 Female

Ethnic Origin: Asian
 African American
 Caucasian
 Latino/a / Hispanic
 Middle Eastern
 First Nation/Native American
 Native Hawaiian/Other Pacific Islander
 Other, Specify _____

Baseline Evaluations: Record clinically significant findings on the Medical History CRF

Physical Exam Date	Weight	Body Temperature	Blood Pressure (mmHg)	Heart Rate (BPM)
_____ - _____ - _____ dd mmm yyyy	_____ kg	_____ °C	_____/_____	_____

Urine Pregnancy Test

Positive
 Negative
 Not Applicable
(Subject is Male, or there is non-child bearing potential, if non childbearing potential record in Medical history)

ECG

Normal
 Abnormal, NOT Clinically Significant
 Abnormal, Clinically Significant
(If abnormal and clinically significant record in Medical history)

Subject Number _____

Initials _____

MAPS Study MT1

CRF

Page 2

Baseline Evaluations: Record clinically significant findings on the Medical History CRF

Clinical Laboratory Tests

Were clinical labs completed? Yes No

Previous Substance Abuse

Previous Alcohol Abuse/dependence

Yes No

If yes, in the last 60 days Yes No

Previous Drug Abuse/dependence

Yes No

If yes, in the last 60 days Yes No

Past Use of Ecstasy

Has the subject ever used "Ecstasy"?

Yes No

If Yes, # of Occasions _____

If Yes, most recent use was:

- Within the last six months
- 6 months to 2 years ago
- 2 years to 5 years ago
- More than 5 years ago

Did subject meet all inclusion criteria? Yes No

If No, Specify _____

Subject Number _____

Initials _____

MAPS Study MT1

CRF

Page 4

Visit #1- Baseline Measures**General Well Being**

	Visit Date	Subject Demeanor and State of Mind enter code 1-6	Subject currently enter code A-C
Visit 1			

1= Very stable and calm
 2= Stable and calm
 3= Slightly stable and calm
 4= Slightly distressed
 5= Distressed
 6= Very distressed

A= Does not face risk of significant deterioration.
B= Probably faces risk of significant deterioration.
C= Faces risk of significant deterioration.

Brief Symptom Inventory (BSI) SCORE		BSI Global Indices SCORE	
1 SOM		Global Severity (GSI)	
2 O-C		Positive Distress (PSDI)	
3 I-S		Positive Total (PST)	
4 DEP			
5 ANX			
6 HOP			
7 PHO			
8 PAR			
9 PSY			

NEO Personality Measure

Record total score for each of the factors listed

Factor	Score
Neuroticism	
Extroversion	
Openness	
Agreeableness	
Conscientiousness	

Subject Number _____

Initials _____

MAPS Study MT1

CRF

Page 5

Visit #1- Baseline Measures

Profile of Mood States (POMS)	
Factor	Scale
Composed-Anxious	
Agreeable-Hostile	
Elated-Depressed	
Confident-Unsure	
Energetic-Tired	
Clearheaded-Confused	

Interpersonal Closeness Measure		Distance (mm)
1	Self	
2	Investigator 1	
3	Investigator 2	
4	Significant Other (relationship) <hr/> <small>Print relationship</small>	
5	The World	
Total Score (add all distances in mm)		

Subject Number _____

Initials _____

MAPS Study MT1

CRF

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Visit #1- Baseline Measures

Columbia Suicide Severity Rating Scale (CSSRS)

Life Time History (CSSRS)

Suicidal Ideation _____

Ideation Intensity _____

Suicidal Behavior _____

Visit 1 Preparatory Session CSSRS

Suicidal Ideation _____

Ideation Intensity _____

Suicidal Behavior _____

Subject Number _____

Initials _____

MAPS Study MT1

CRF

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Experimental Session # 1

Urine Pregnancy Test

- Positive
- Negative
- Not Applicable
(Subject is Male, Non-child bearing potential,
If non childbearing potential clarify in Medical history)

Dosing Visit 2

Date of Dose

____ - ____ - ____
dd mmm yyyy

Dose administered, record time:

____ : ____
(24 hr clock)

Record package number

Supplemental Administered?

Yes No

If yes, Record time:

____ : ____
(24 hr clock)

If yes, Record package number:

Subject Number _____

Initials _____

MAPS Study MT1

CRF

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Experimental Session # 1**Visit 2 Physiological measures, body temperature and SUDS**

Record result and time of measurement. Body temperature should be recorded in Centigrade.

	Baseline Value (pre-dose) (____:____) time 24 hr clock	Mid Point (3 hrs +/- 30 Minutes) (____:____) time 24 hr clock	End Point (7 hrs +/- 30 Minutes) (____:____) time 24 hr clock
Blood Pressure (mm/Hg)	/		
Pulse (BPM)			
Body Temperature C°			
SUDS			

	Record Time of Highest Value time 24 hr clock	Record Highest Value	Was Value ever over:	If yes, how long? If < than 1 hr record min. only.
Blood Pressure reading where Systolic is highest (mm/Hg)	(____:____)	/	160/110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
Blood Pressure reading where Diastolic is highest (mm/Hg)	(____:____)	/	160/110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
Pulse (BPM)	(____:____)		110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
Body Temperature C°	(____:____)		1 degree C° above baseline? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
SUDS	(____:____)			

Subject Number _____

Initials _____

MAPS Study MT1

CRF

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Experimental Session #1- Integration and Follow up

Columbia Suicide Severity Rating Scale (CSSRS)

Visit 2 Pre Drug Administration CSSRS

Suicidal Ideation _____

Ideation Intensity _____

Suicidal Behavior _____

Visit 2 Post Drug Administration CSSRS

Suicidal Ideation _____

Ideation Intensity _____

Suicidal Behavior _____

Visit 3 Integrative Session 1 Day Post Drug Administration CSSRS

Suicidal Ideation _____

Ideation Intensity _____

Suicidal Behavior _____

Subject Number _____ Initials _____

MAPS Study MT1

CRF

Experimental Session #1- Integration and Follow up

Visit 2 BSI Pre Drug Administration

Brief Symptom Inventory (BSI)		BSI Global Indices	
SCORE		SCORE	
1 SOM		Global Severity (GSI)	
2 O-C		Positive Distress (PSDI)	
3 I-S		Positive Total (PST)	
4 DEP			
5 ANX			
6 HOP			
7 PHO			
8 PAR			
9 PSY			

Visit 2 BSI Post Drug Administration

1 SOM		Global Severity (GSI)	
2 O-C		Positive Distress (PSDI)	
3 I-S		Positive Total (PST)	
4 DEP			
5 ANX			
6 HOP			
7 PHO			
8 PAR			
9 PSY			

Visit 3 BSI Integrative Session 1 Day Post Drug Administration

1 SOM		Global Severity (GSI)	
2 O-C		Positive Distress (PSDI)	
3 I-S		Positive Total (PST)	
4 DEP			
5 ANX			
6 HOP			
7 PHO			
8 PAR			
9 PSY			

Subject Number _____

Initials _____

MAPS Study MT1

CRF

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Experimental Session #1- Integration and Follow up**Visit 2 Post Drug Administration**

Profile of Mood States (POMS)	
Factor	Scale
Composed-Anxious	
Agreeable-Hostile	
Elated-Depressed	
Confident-Unsure	
Energetic-Tired	
Clearheaded-Confused	

Interpersonal Closeness Measure		Distance (mm)
1	Self	
2	Investigator 1	
3	Investigator 2	
4	Significant Other (relationship) <hr/> Print relationship	
5	The World	
Total Score (add all distances in mm)		

Visit 3 Integrative Session 1 Day Post Drug Administration

Profile of Mood States (POMS)	
Factor	Scale
Composed-Anxious	
Agreeable-Hostile	
Elated-Depressed	
Confident-Unsure	
Energetic-Tired	
Clearheaded-Confused	

Interpersonal Closeness Measure		Distance (mm)
1	Self	
2	Investigator 1	
3	Investigator 2	
4	Significant Other (relationship) <hr/> Print relationship	
5	The World	
Total Score (add all distances in mm)		

Subject Number _____

Initials _____

MAPS Study MT1

CRF

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Experimental Session #1- Integration and Follow up

Investigator 1 belief of condition assignment	Investigator 2 belief of condition assignment	Subject belief of condition assignment
Investigator name:	Investigator name:	
<input type="checkbox"/> MDMA 25 mg <input type="checkbox"/> MDMA 125 mg	<input type="checkbox"/> MDMA 25 mg <input type="checkbox"/> MDMA 125 mg	<input type="checkbox"/> MDMA 25 mg <input type="checkbox"/> MDMA 125 mg
<input type="checkbox"/> Not at all certain <input type="checkbox"/> Somewhat certain <input type="checkbox"/> Certain <input type="checkbox"/> Very certain	<input type="checkbox"/> Not at all certain <input type="checkbox"/> Somewhat certain <input type="checkbox"/> Certain <input type="checkbox"/> Very certain	<input type="checkbox"/> Not at all certain <input type="checkbox"/> Somewhat certain <input type="checkbox"/> Certain <input type="checkbox"/> Very certain

General Well Being

Days Post Experimental Session #1	Date dd-mmm-yyyy	Subject Demeanor and State of Mind enter code 1-6	Subject currently enter code A-C
Day of Experimental Session #1 Post Session (V2)			
Day 1- Day of Integrative Session (V3)			

1= Very stable and calm
 2= Stable and calm
 3= Slightly stable and calm
 4= Slightly distressed
 5= Distressed
 6= Very distressed

A= Does not face risk of significant deterioration.
B= Probably faces risk of significant deterioration.
C= Faces risk of significant deterioration.

Experimental Session #1- Integration and Follow up**Spontaneously Reported Side Effects Post Experimental Session**

Please record the maximum intensity of any spontaneously reported effects. If no reactions are present for an entire day, check the "none" box. Only use as many spaces as needed for a given day. For example, if only two reactions are present for a given day, complete two columns and leave the remaining columns blank.

Days Post Exp. Session #1	Check if None	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code
Day of Session #1 (V2)	<input type="checkbox"/>										
Day 1- Day of Integrative session (V3)	<input type="checkbox"/>										

Reaction Codes-

A- Anxiety
 B- Diarrhea
 C- Difficulty concentrating
 D- Dizziness
 E- Drowsiness
 F- Dry Mouth
 G- Fatigue
 H- Headache
 I- Impaired Judgment
 J- Impaired Gait/balance
 K- Increased Irritability
 L- Insomnia
 M- Jaw clenching, tight jaw

N- Lack of appetite
 O- Low Mood
 P- Muscle tension
 Q- Nausea
 R- Nystagmus
 S- Parasthesias
 T- Perspiration
 U- Restlessness
 V- Ruminations
 W- Sensitivity to Cold
 X- Thirst
 Y- Unusual Somatic Sensations
 Z- Weakness

Intensity Codes-

1= Mild
 2= Moderate
 3= Severe

Mild: no limitation in normal daily activity

Moderate: some limitation in normal daily activity

Severe: unable to perform normal daily activity

Subject Number _____

Initials _____

MAPS Study MT1

CRF

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Experimental Session # 2

Urine Pregnancy Test

- Positive
- Negative
- Not Applicable

(Subject is Male, Non-child bearing potential,
If non childbearing potential clarify in Medical history)

Dosing Visit 4

Date of Dose

_____-_____-_____
dd mmm yyyy

Dose administered, record time:

_____:_____
(24 hr clock)

Record package number

Supplemental Administered?

Yes No

If yes, Record time:

_____:_____
(24 hr clock)

If yes, Record package number:

Subject Number _____

Initials _____

MAPS Study MT1

CRF

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Experimental Session # 2**Visit 4 Physiological measures, body temperature and SUDS**

Record result and time of measurement. Body temperature should be recorded in Centigrade.

	Baseline Value (pre-dose) (____:____) time 24 hr clock	Mid Point (3 hrs +/- 30 Minutes) (____:____) time 24 hr clock	End Point (7 hrs +/- 30 Minutes) (____:____) time 24 hr clock
Blood Pressure (mm/Hg)	/		
Pulse (BPM)			
Body Temperature C°			
SUDS			

	Record Time of Highest Value time 24 hr clock	Record Highest Value	Was Value ever over:	If yes, how long? If < than 1 hr record min. only.
Blood Pressure reading where Systolic is highest (mm/Hg)	(____:____)	/	160/110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
Blood Pressure reading where Diastolic is highest (mm/Hg)	(____:____)	/	160/110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
Pulse (BPM)	(____:____)		110? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
Body Temperature C°	(____:____)		1 degree C° above baseline? <input type="checkbox"/> Yes <input type="checkbox"/> No	____h ____min
SUDS	(____:____)			

Subject Number _____

Initials _____

MAPS Study MT1

CRF

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Experimental Session #2- Integration and Follow up

Columbia Suicide Severity Rating Scale (CSSRS)

Visit 4 Pre Drug Administration CSSRS

Suicidal Ideation _____

Ideation Intensity _____

Suicidal Behavior _____

Visit 4 Post Drug Administration CSSRS

Suicidal Ideation _____

Ideation Intensity _____

Suicidal Behavior _____

Visit 5 Integrative Session 1 Day Post Drug Administration CSSRS

Suicidal Ideation _____

Ideation Intensity _____

Suicidal Behavior _____

Subject Number _____

Initials _____

MAPS Study MT1

CRF

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Experimental Session #2- Integration and Follow up**Visit 4 BSI Pre Drug Administration**

Brief Symptom Inventory (BSI)		BSI Global Indices	
SCORE		SCORE	
1 SOM		Global Severity (GSI)	
2 O-C		Positive Distress (PSDI)	
3 I-S		Positive Total (PST)	
4 DEP			
5 ANX			
6 HOP			
7 PHO			
8 PAR			
9 PSY			

Visit 4 BSI Post Drug Administration

1 SOM		Global Severity (GSI)	
2 O-C		Positive Distress (PSDI)	
3 I-S		Positive Total (PST)	
4 DEP			
5 ANX			
6 HOP			
7 PHO			
8 PAR			
9 PSY			

Visit 5 BSI Integrative Session 1 Day Post Drug Administration

1 SOM		Global Severity (GSI)	
2 O-C		Positive Distress (PSDI)	
3 I-S		Positive Total (PST)	
4 DEP			
5 ANX			
6 HOP			
7 PHO			
8 PAR			
9 PSY			

12/11/09

Subject Number _____

Initials _____

MAPS Study MT1

CRF

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Experimental Session #2 Integration and Follow up**Visit 4 Post Drug Administration**

Profile of Mood States (POMS)	
Factor	Scale
Composed-Anxious	
Agreeable-Hostile	
Elated-Depressed	
Confident-Unsure	
Energetic-Tired	
Clearheaded-Confused	

Interpersonal Closeness Measure		Distance (mm)
1	Self	
2	Investigator 1	
3	Investigator 2	
4	Significant Other (relationship) <hr/> Print relationship	
5	The World	
Total Score (add all distances in mm)		

Visit 5 Integrative Session 1 Day Post Drug Administration

Profile of Mood States (POMS)	
Factor	Scale
Composed-Anxious	
Agreeable-Hostile	
Elated-Depressed	
Confident-Unsure	
Energetic-Tired	
Clearheaded-Confused	

Interpersonal Closeness Measure		Distance (mm)
1	Self	
2	Investigator 1	
3	Investigator 2	
4	Significant Other (relationship) <hr/> Print relationship	
5	The World	
Total Score (add all distances in mm)		

Subject Number _____

Initials _____

MAPS Study MT1

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Experimental Session #2- Integration and Follow up

Investigator 1 belief of condition assignment	Investigator 2 belief of condition assignment	Subject belief of condition assignment
Investigator name:	Investigator name:	
<input type="checkbox"/> MDMA 25 mg <input type="checkbox"/> MDMA 125 mg	<input type="checkbox"/> MDMA 25 mg <input type="checkbox"/> MDMA 125 mg	<input type="checkbox"/> MDMA 25 mg <input type="checkbox"/> MDMA 125 mg
<input type="checkbox"/> Not at all certain <input type="checkbox"/> Somewhat certain <input type="checkbox"/> Certain <input type="checkbox"/> Very certain	<input type="checkbox"/> Not at all certain <input type="checkbox"/> Somewhat certain <input type="checkbox"/> Certain <input type="checkbox"/> Very certain	<input type="checkbox"/> Not at all certain <input type="checkbox"/> Somewhat certain <input type="checkbox"/> Certain <input type="checkbox"/> Very certain

General Well Being

Days Post Experimental Session #2	Date dd-mmm-yyyy	Subject Demeanor and State of Mind enter code 1-6	Subject currently enter code A-C
Day of Experimental Session #2 Post Session (V4)			
Day 1- Day of Integrative Session (V5)			

1= Very stable and calm
 2= Stable and calm
 3= Slightly stable and calm
 4= Slightly distressed
 5= Distressed
 6= Very distressed

A= Does not face risk of significant deterioration.
B= Probably faces risk of significant deterioration.
C= Faces risk of significant deterioration.

Subject Number _____

Initials _____

MAPS Study MT1

CRF

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Experimental Session #2- Integration and Follow up

Spontaneously Reported Side Effects Post Experimental Session

Please record the maximum intensity of any spontaneously reported effects. If no reactions are present for an entire day, check the "none" box. Only use as many spaces as needed for a given day. For example, if only two reactions are present for a given day, complete two columns and leave the remaining columns blank.

Days Post Exp. Session #2	Check if None	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code
Day of Session #2 (V4)	<input type="checkbox"/>										
Day 1- Day of Integrative session (V5)	<input type="checkbox"/>										

Reaction Codes-

- A- Anxiety
- B- Diarrhea
- C- Difficulty concentrating
- D- Dizziness
- E- Drowsiness
- F- Dry Mouth
- G- Fatigue
- H- Headache
- I- Impaired Judgment
- J- Impaired Gait/balance
- K- Increased Irritability
- L- Insomnia
- M- Jaw clenching, tight jaw

- N- Lack of appetite
- O- Low Mood
- P- Muscle tension
- Q- Nausea
- R- Nystagmus
- S- Parasthesis
- T Perspiration
- U- Restlessness
- V- Ruminations
- W- Sensitivity to Cold
- X- Thirst
- Y- Unusual Somatic Sensations
- Z- Weakness

Intensity Codes-

- 1= Mild
 - 2= Moderate
 - 3= Severe
- Mild:** no limitation in normal daily activity
- Moderate:** some limitation in normal daily activity
- Severe:** unable to perform normal daily activity

Subject Number _____

Initials _____

MAPS Study MT1

CRF

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Post Experimental Sessions Integration and Follow up**General Well Being: Measured for 7 days post Visit 5 and at the 1 and 2 month follow up**

Days Post Visit 5		Date dd-mmm-yyyy	Subject Demeanor and State of Mind enter code 1-6	Subject currently enter code A-C
Day 6	<input type="checkbox"/> Phone <input type="checkbox"/> Visit			
Day 7	<input type="checkbox"/> Phone <input type="checkbox"/> Visit			
Day 8	<input type="checkbox"/> Phone <input type="checkbox"/> Visit			
Day 9	<input type="checkbox"/> Phone <input type="checkbox"/> Visit			
Day 10	<input type="checkbox"/> Phone <input type="checkbox"/> Visit			
Day 11	<input type="checkbox"/> Phone <input type="checkbox"/> Visit			
Day 12	<input type="checkbox"/> Phone <input type="checkbox"/> Visit			
1 Month (D32)	<input type="checkbox"/> Phone <input type="checkbox"/> Visit			
2 Months (D62)	<input type="checkbox"/> Phone <input type="checkbox"/> Visit			

1= Very stable and calm
2= Stable and calm
3= Slightly stable and calm
4= Slightly distressed
5= Distressed
6= Very distressed

A= Does not face risk of
significant deterioration.
B= Probably faces risk of
significant deterioration.
C= Faces risk of significant
deterioration.

Post Experimental Sessions Integration and Follow up**Spontaneously Reported Side Effects Post Experimental Session**

Please record the maximum intensity of any spontaneously reported effects. Record any reaction still ongoing at day 12 on the Adverse Events Page. If no reactions are present for an entire day, check the "none" box. Only use as many spaces as needed for a given day. For example, if only two reactions are present for a given day, complete two columns and leave the remaining columns blank.

Days post Visit 5	Check if None	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code	Reaction Code/ Intensity code
Day 6	<input type="checkbox"/>										
Day 7	<input type="checkbox"/>										
Day 8	<input type="checkbox"/>										
Day 9	<input type="checkbox"/>										
Day 10	<input type="checkbox"/>										
Day 11	<input type="checkbox"/>										
Day 12	<input type="checkbox"/>										

Reaction Codes-

A- Anxiety
 B- Diarrhea
 C- Difficulty concentrating
 D- Dizziness
 E- Drowsiness
 F- Dry Mouth
 G- Fatigue
 H- Headache
 I- Impaired Judgment
 J- Impaired Gait/balance
 K- Increased Irritability
 L- Insomnia
 M- Jaw clenching, tight jaw

N- Lack of appetite
 O- Low Mood
 P- Muscle tension
 Q- Nausea
 R- Nystagmus
 S- Parasthesias
 T- Perspiration
 U- Restlessness
 V- Ruminations
 W- Sensitivity to Cold
 X- Thirst
 Y- Unusual Somatic Sensations
 Z- Weakness

Intensity Codes-

1= Mild
 2= Moderate
 3= Severe

Mild: no limitation in normal daily activity

Moderate: some limitation in normal daily activity

Severe: unable to perform normal daily activity

Subject Number _____

Initials _____

MAPS Study MT1

CRF

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Post Experimental Sessions Integration and Follow up

Columbia Suicide Severity Rating Scale (CSSRS)

Day 6 -2 Days Post Experimental Sessions CSSRS

Suicidal Ideation _____

Ideation Intensity _____

Suicidal Behavior _____

Day 12- 8 Days Post Experimental Sessions CSSRS

Suicidal Ideation _____

Ideation Intensity _____

Suicidal Behavior _____

1 Month Follow-up Post Experimental Sessions CSSRS (D32)

Suicidal Ideation _____

Ideation Intensity _____

Suicidal Behavior _____

2 Month Follow-up Post Experimental Sessions CSSRS (D62)

Suicidal Ideation _____

Ideation Intensity _____

Suicidal Behavior _____

Subject Number _____

Initials _____

MAPS Study MT1

CRF

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Post Experimental Sessions Integration and Follow up

2 Month Follow-up Post Experimental Sessions (D62)

NEO Personality Measure	
Record total score for each of the factors listed	
Factor	Score
Neuroticism	
Extroversion	
Openness	
Agreeableness	
Conscientiousness	

Complete CRF Series 50

Subject Number _____

Initials _____

MAPS Study MT1

Con Med CRF

Page Series 50. if last page

Concomitant Medications- Baseline and Study Duration

- Record psychotropic medications previously used/tapered **and** psychotropic and other prescription and non-prescriptions medications subject is taking at baseline. For past and baseline Meds check the Prestudy box (include start date if known) and provide Medical History Diagnosis and Prestudy Diagnosis number if applicable. Provide route, dose and stop date/continuing for all medications, tapered medications require a stop date.
- Record **all new medications** taken after visit 1 through termination visit. Provide route and start date. Provide AE# (from AE page) or complete Other Reason for Treatment. Check the Continuing box if continuing at study termination.

CHECK IF NONE

Medication	Route ^a code 1-10	Start Date (dd-mmm-yyyy)	Stop Date (dd-mmm-yyyy)	Reason for Treatment Complete at least one column			
				Medical History Diag #	Prestudy Disorder Code ^b	AE#	Other
		<input type="checkbox"/> Prestudy <input type="checkbox"/> Taper	<input type="checkbox"/> Continuing				
		<input type="checkbox"/> Prestudy <input type="checkbox"/> Taper	<input type="checkbox"/> Continuing				
		<input type="checkbox"/> Prestudy <input type="checkbox"/> Taper	<input type="checkbox"/> Continuing				
		<input type="checkbox"/> Prestudy <input type="checkbox"/> Taper	<input type="checkbox"/> Continuing				
		<input type="checkbox"/> Prestudy <input type="checkbox"/> Taper	<input type="checkbox"/> Continuing				

^a Codes for Route; 1=oral , 2= IV, 3= injection, 4=topical, 5=transdermal, 6=intranasal, 7=inhalaional, 8=intravitreal, 9=vaginal, 10=rectal

^b Code for prestudy disorders; 1= Depression, 2 = Panic Disorder, 3 = General Anxiety Disorder (GAD), 4 = Insomnia / sleeping difficulty, 5 = Obsessive compulsive disorder (OCD), 6 = PTSD

Subject Number _____

Initials _____

MAPS Study MT1

AE CRF

Page Series 51. _____ √ if last page

Adverse Events **CHECK IF NONE**

Record all Adverse Events and Serious Adverse Events through the Visit 5. After Visit 5 through 2 month follow up record only AEs that require a physician visit or consultation. Record all SAEs through the entire study. Record any exacerbations of a Medical History Diagnosis. Record side effects on the Side Effects CRF unless the reactions are still present at day 12.

AE #	Adverse event Diagnosis	Serious ^a	Onset date (dd/mmm/yyyy)	Resolution date (dd/mmm/yyyy)	Severity ^b	Frequency ^c	Action taken for Study ^d	Action taken-treatment ^e	Action Taken Other Specify	Outcome ^f	Relationship to Drug ^g

a
Serious?
1 = Serious*
2 = Not serious

* Serious = Fatal, life-threatening, requires prolonged hospitalization, results in persistent or significant disability, or requires medical or surgical intervention to prevent one of the outcomes defined as "serious" listed above.

b
Severity
1 = Mild
2 = Moderate
3 = Severe

c
Frequency
1 = Single/Intermittent
2 = Continuous

d
Action Taken: Study
1 = None
2 = Interrupted session
3 = Delayed experimental session
4 = Discontinued experimental session

e
Action Taken: Treatment
1 = None
2 = Procedure or therapy
3 = Blood or Blood products
4 = Withdrawn from study due to AE
5 = Prescription Med
6 = Non Prescription Med
7 = Hospitalization
8 = IV Fluids
9 = Other specify

f
Outcome
1 = Full recovery/return to baseline
2 = Persists, diminishing
3 = Persists, worsening
4 = Persists, the same
5 = Alive with sequelae
6 = Death

g
Relationship to Drug
1 = Not related
2 = Possibly related
3 = Probably related