NIDA-CTN Interim Monitoring Report Form

NIDA-CTN-	Protocol Title:	
Node Name:	Site ID:	Visit Date(s):
Node Principal Investigator (PI):		
Node Protocol PI:	Site Monitor:	
Site PI:	Node Protocol Coordinator:	

Study Type: ☐ Behavioral ☐ Medication ☐ Combination ☐ Other

Purpose of Monitoring Visit: (check all that apply)

- ☐ Comprehensive
- ☐ Regulatory Binder (Sections I, II)
- ☐ Informed Consent (Sections III, IV)
- ☐ Protocol Compliance/CRFs (Sections V, VI, VII)
- ☐ Pharmacy Review (Sections IV, VII)
- ☐ Study Facilities (Sections IX, X)
- ☐ Other

Site Visit Attendees:		

Study Status at this Visit	☐ In progress	☐ Completed	☐ Discontinued

Participant Enrollment Status (cumulative) *Can be modified by protocol.*						
# Consented	# Screened	# Rand.	# Active	# F/U	# Completed	# Withdrawn

Changes since the last visit.

1. Study Site Address: _____ ☐ No Changes

2. Changes in study team members or contact information?
_____ ☐ No Changes

Follow up on issues from the previous visit(s): ☐ No issues

Issue	Date Identified	Action to be taken	Resolved? Y/N If no, explain in comments.
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No

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Complete the following checklist. Address outstanding issues on the Comment Page, referencing back to the item number:
Yes = All versions of the following essential documents are present and up-to-date
No = All versions are not present — explanation required in the comments section
N/A = Not Applicable for Protocol
N/R = Not Reviewed this visit

	Yes	No	N/A	N/R
I Review of Study Binder / Regulatory Materials:				
Are current, fully executed versions of the following present in the Study Binder?	☐	☐	☐	☐
A. Protocol and protocol amendments with corresponding completed signature pages	☐	☐	☐	☐
B. Protocol SOPs	☐	☐	☐	☐
C. Sample IRB approved consent forms with IRB date and stamp	☐	☐	☐	☐
D. Sample copies of all protocol CRFs	☐	☐	☐	☐
E. List of CRFs used as Source Documents	☐	☐	☐	☐
F. Curriculum vitae / statement of qualifications for protocol staff	☐	☐	☐	☐
G. Copies of licenses / certifications for protocol staff	☐	☐	☐	☐
H. Documentation of required CTN training for protocol staff	☐	☐	☐	☐
I. Investigator s Brochure for all investigational products	☐	☐	☐	☐
J. FDA 1572 / Statement of Investigator Obligations	☐	☐	☐	☐
K. Documentation of IRB approval of any study related materials	☐	☐	☐	☐
L. Appropriate lab certifications and normal ranges	☐	☐	☐	☐
M. IRB Assurance and IRB membership	☐	☐	☐	☐
N. DEA certification	☐	☐	☐	☐
Comments:				

II Site/Other				
A. Are all required items/documents present?	☐	☐	☐	☐
B. Are all equipment / supplies vital to the conduct of the protocol being maintained appropriately?	☐	☐	☐	☐
C. Are Site Visit and Monitor Logs being utilized?	☐	☐	☐	☐
D. Are the Investigator and his/her staff maintaining records of correspondence related to the conduct of the study?	☐	☐	☐	☐

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	Yes	No	N/A	N/R
Comments:				
III Informed Consents / Enrollment				
A. Are signed originals and current IRB approved informed consents on file for all participants?	☐	☐		☐
B. Are Screening Logs being maintained?	☐	☐		☐
C. Are Master Enrollment Logs being maintained?	☐	☐		☐
Comments:				
IV Review of Study Drugs and Drug Accountability Records				
A. Are drug supplies properly stored in a secured area?	☐	☐	☐	☐
B. Have all drug supplies been dispensed by appropriate persons?	☐	☐	☐	☐
C. Are copies of drug shipment records current and accurate/dated and signed?	☐	☐	☐	☐
D. Are drug dispensing and accountability records for supplied medications correct and up to date?	☐	☐	☐	☐
E. Is drug being dispensed according to protocol?	☐	☐	☐	☐
F. Have outdated/expired supplies been returned?	☐	☐	☐	☐
G. Are drug supplies and randomization envelopes adequate?	☐	☐	☐	☐
H. Has the blind been maintained?	☐	☐	☐	☐
I. Are blinded randomization envelopes accounted for and intact?	☐	☐	☐	☐
Comments:				
V Protocol Compliance (for participant charts reviewed)				
A. Were screening procedures followed correctly?	☐	☐	☐	☐
B. All participants meet inclusion/exclusion criteria	☐	☐	☐	☐
C. Were randomization procedures followed correctly?	☐	☐	☐	☐
D. Were AE s appropriately reported, documented, assessed and followed to resolution when applicable?	☐	☐	☐	☐
E. Participant visits and procedures follow protocol schedule	☐	☐		☐

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	Yes	No	N/A	N/R
F. Are missed visits and no-shows properly handled and documented?	☐	☐	☐	☐
G. Was study intervention delivered according to protocol? (behavioral trials)	☐	☐	☐	☐
H. SAEs				
1. All SAEs reported and documented according to procedure and available information	☐	☐	☐	
2. Copies of SAE final reports on file	☐	☐	☐	
3. Do any SAEs still require follow-up?	☐	☐	☐	
4. SAEs reported to IRB	☐	☐	☐	
5. Any unreported SAEs detected	☐	☐	☐	

Comments:

VI Case Report Forms/Source Documentation

A. Are CRFs/corresponding source documents available for review?	☐	☐		☐
B. Do source documents allow for CRF verification?	☐	☐		☐
C. Are CRFs complete, legible and accurate? (corrections have been made appropriately)	☐	☐		☐
D. Have CRFs been submitted in a timely manner?	☐	☐	☐	☐
E. Have data queries been completed and submitted appropriately?	☐	☐	☐	☐

Comments:

VII Protocol Violation(s)

A. Have any protocol violation(s), not previously noted, been reviewed and appropriately documented?	☐	☐	☐	☐

Comments:

VIII Central Laboratory Procedures

A. Are samples being collected and stored according to the protocol specifications?	☐	☐	☐	☐
B. Are Shipment records and procedures documented appropriately?	☐	☐	☐	☐
Date of last shipment: __/__ __/__ (*mm/dd/yyyy*)				
C. Clinical significance of laboratory data has been	☐	☐	☐	☐

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	Yes	No	N/A	N/R
assessed and documented appropriately by medical personnel.				

Comments:

IX Study Facilities/Recruitment

A. Do study site facilities remain suitable?	☐	☐		☐
B. Does staff remain suitable?	☐	☐	☐	☐
C. Is current participant recruitment plan adequate?	☐	☐	☐	☐

Comments:

X Status of the Site

A. Has anything changed at the site that impacts the conduct of the study?	☐	☐	☐	☐

Comments:

XI Issues Identified	Action Required (describe)	Resolved during visit
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No

Attached to this report are the following documents: (Examples: Data Clarification Form, Protocol Violation Log, Participant Monitoring Log, etc.)

☐ _____ ☐ _____

☐ _____ ☐

Summary:

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Next Visit Scheduled _____ / _____ /

I certify that the above information is, to the best of my knowledge, correct and accurate.

Monitor s Name(s) _____

Signature(s) _____ / /

_____ / /

_____ / /