NIDA-CTN Interim Monitoring Report Form

NIDA-CTN-	Protocol Title:	
Node ID and Name:	Site ID and Name:	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)

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

Site Visit Attendees:

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

Study related changes since the last visit:

1. Study Site Address?

_____ ☐ No Changes

2. Changes in study team members or contact information?

_____ ☐ No Changes

	Yes	No	N/A	N/R
I Review of Regulatory Files				
Complete the following checklist indicating one of the following choices for each item: 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 at this visit				
A. Protocol and protocol amendments with corresponding completed signature pages	☐	☐	☐	☐

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	Yes	No	N/A	N/R
B. Protocol SOPs/SOM	☐	☐	☐	☐
C. IRB approved consent forms and IRB approved (if applicable) HIPAA authorization	☐	☐	☐	☐
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 professional 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	☐	☐	☐	☐
O. Site Visit and Monitor Logs	☐	☐		☐
P. Records of correspondence maintained between the Investigator and his/her staff related to the conduct of the study for the following:				
NIDA/LN Correspondence	☐	☐	☐	☐
Node/CTP	☐	☐	☐	☐
Other/conference call and meeting minutes	☐	☐	☐	☐
IRB	☐	☐	☐	☐
QA	☐	☐	☐	☐
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 all other study related logs being maintained?	☐	☐	☐	☐
Comments:				
III Informed Consents / Enrollment				

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	Yes	No	N/A	N/R
A. Are signed originals of current IRB approved informed consents on file for all participants and were consents properly executed?	☐	☐		☐
B. Are signed originals of current IRB approved (if applicable) HIPAA authorizations file for all participants and were authorizations properly executed?	☐	☐	☐	☐
C. Are Master Enrollment Logs being maintained?	☐	☐		☐
Comments:				
IV Review of Study Medication and Drug Accountability Records				
A. Is documentation present for ALL study medications received from the sponsor?	☐	☐	☐	☐
B. Are ALL study medications properly stored and in a secure area?	☐	☐	☐	☐
C. Are ALL study medication supplies sent from the sponsor accounted for by actual count, and consistent with up-to-date drug accountability records?	☐	☐	☐	☐
D. Have ALL study medications been prescribed and dispensed per protocol?	☐	☐	☐	☐
E. Are ALL study medications assigned to participants accounted for by actual count and consistent with up-to-date participant drug accountability records?	☐	☐	☐	☐
F. Have protocol specific SOPs been followed for the disposition of expired and/or unused study medications?	☐	☐	☐	☐
G. Are study medication supplies adequate?	☐	☐	☐	☐
H. Since the last monitoring visit, has the medication blind been maintained?	☐	☐	☐	☐
Comments:				
V Protocol Compliance (for participant charts reviewed)				
A. Were all procedures to determine participant eligibility followed correctly?	☐	☐		☐
B. Do all participants meet inclusion/exclusion	☐	☐	☐	☐

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	Yes	No	N/A	N/R
criteria?				
C. Were randomization procedures followed correctly?	☐	☐	☐	☐
D. Have all non-medication blinds been maintained per protocol?	☐	☐	☐	☐
E. Were AEs appropriately reported, documented, assessed and followed to resolution when applicable?	☐	☐	☐	☐
F. Do participant visits and procedures follow protocol schedule?	☐	☐		☐
G. Are missed visits and no-shows properly handled and documented?	☐	☐	☐	☐
H. Did all participants receive the study intervention or TAU according to protocol?	☐	☐	☐	☐
I. SAEs				
1. Have SAEs been reported and documented according to individual protocol procedures and available information?	☐	☐	☐	☐
2. Are all copies of SAE final reports on file as appropriate?	☐	☐	☐	☐
3. Have all SAEs been appropriately followed up to resolution?	☐	☐	☐	☐
4. Have all SAEs been reported to the local IRB (s) as per local policies?	☐	☐	☐	☐
5. Do all SAEs have a corresponding AE recorded?	☐	☐	☐	☐
Comments:				
VI Case Report Forms/Source Documentation				
A. Are source documents available for review?	☐	☐		☐
B. Do source documents allow for CRF verification?	☐	☐		☐
C. Are source documents free of numerous, serious, significant, or recurrent errors?	☐	☐		☐
D. Are CRFs available for review?	☐	☐		☐
E. Are CRFs free of numerous, serious, significant or recurrent errors?	☐	☐		☐
F. Are data queries being appropriately resolved?	☐	☐	☐	☐
G. Are QA monitoring queries being appropriately resolved?	☐	☐	☐	☐
Comments:				

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	Yes	No	N/A	N/R
VII Protocol Violation(s)				
A. Are site personnel in compliance with the protocol?	☐	☐		☐
B. If protocol violations have occurred, have they been properly documented and reported?	☐	☐	☐	☐
Comments:				
VIII Biological Laboratory Procedures				
A. Are samples being collected and stored according to the protocol specifications?	☐	☐	☐	☐
B. Are shipment records and procedures documented appropriately?	☐	☐	☐	☐
C. Has clinical significance of laboratory data been assessed and documented appropriately by medical personnel?	☐	☐	☐	☐
Comments:				
IX Study Facilities/Recruitment/Staffing				
A. Do study site facilities remain suitable?	☐	☐		☐
B. Does research staff remain suitable?	☐	☐		☐
C. Is the protocol staff actively addressing all recruitment issues?	☐	☐	☐	☐
Comments:				

X Summary

XI Next Scheduled Visit: / /

XII Optional Attachments

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

☐ **No Attachments**

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☐ _____ ☐ _____
☐ _____ ☐ _____

XIII Continuing and Current Local QA Issues ☐ **No Issues**

Date First Identified	Local QA Issues	Action Required/Updates	Resolved? If no, provide update.
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No

XIV Follow-up Issues from previous NIDA Contract Monitors/LN Reports

☐ **No Issues**

Date First Identified	NIDA Contract Monitor/ LN Issues	Action Required/Updates	Resolved? If no, provide update.
			☐ Yes ☐ No
			☐ Yes ☐ No
			☐ Yes ☐ No

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

Monitor's Name(s) _____
_____