CTP PROTOCOL PRE-INITIATION WORKSHEET (V5 - 05 July 2001)

Protocol#: CTN-_____ Protocol Name:_____

Protocol Type (circle one): BEH MED COMB OTHER

Node: _____ CTP Name: _____

Date: _____ Completed by (name): _____

Item	Yes	No	NA	Notes
Community Treatment Program				
1. IRB approval received for current protocol, consent form, amendments, brochures & local recruitment material				
2. Protocol signature page returned to Lead Investigator				
3. Node CRFs and Instructions received				
4. Protocol operations manual(s) received and available for reference. Should contain complete information on all aspects of study.				
5. Local SOPs (e.g., Clinic Policies) compiled and available for reference				
6. Facility (clinic) emergency plan available				
7. Referral sources listed				
8. State Health Department Reporting Requirements documented, such as a. Communicable Diseases b. Limits to confidentiality c. Other (e.g., child, elder or sexual abuse)				
9. Information flow among study staff documented and understood.				
10. Participant source and CRF binders created with appropriate sections.				
11. CRFs in participant CRF binders or otherwise available				
12. Blank copies of required study forms (e.g., progress notes, lab requisitions, etc.) are available.				
13. Regulatory binder contains (or notes location of):				
a. Protocol				
b. Protocol amendments				
c. Samples of approved informed consent forms				
d. Sample CRFs				

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Item	Yes	No	NA	Notes
e. Assurance				
f. IRB membership listing				
g. Certificate of Confidentiality				
h. IRB Correspondence, including approval letters for: 1. Correct version of protocol 2. Informed consent 3. Local recruitment materials				
i. Protocol Staff: 1. Roster with roles, responsibilities, and qualifications 2. Signature Logs 3. CV's of staff 4. Licensure/Certifications				
j. Lab Certification and Normal Ranges, if applicable				
k. Copy of Protocol Signature Page AND Statement of Investigator Obligations (e.g., FDA 1572 for pharmacotherapy trials)				
l. Investigator's Brochure or product insert (for pharmacotherapy trials)				
m. DEA Certification, when required				
n. State Drug Regulatory certificates, when required				
o. Site-Sponsor Correspondence				
p. Communications Log				
q. Site Visit/Monitor Log				
r. Monitor Reports				
s. Other Correspondence				
t. Drug accountability documentation /pharmacy plan, if applicable				
u. SAE Reporting System, including a serious Adverse Event Log				
v. Operations manual (location only)				
w. Clinic Emergency Plan (location only)				
x. Participant binders (location only)				

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Item	Yes	No	NA	Notes
y. Participant tracking log (location only)				
z. Other, as required				
14. Procedure and supporting documents for participant reimbursement				
15. Recruitment procedures in place				
16. Procedures in place for breaking the blind (e.g., when knowledge is needed to provide proper emergency care)				
17. CTP management has been informed about the upcoming study and their role in participation				
18. Non-protocol CTP staff (e.g., receptionist, telephone operator, etc.) has been informed of the study and instructed how to handle participants' calls and questions				
19. Participating CTP staff have been trained in all required modules.				
20. Plans made for conducting any remaining CTP training required.				
21. Procedures in place for assuring safety of RA and other study staff.				
22. Procedures in place for handling participant medical emergencies				
23. Procedures in place for handling participant psychiatric emergencies				
24. Arrangements made for analysis of samples, e.g. contract with laboratory				
25. Arrangements made for interpretation of ECGs				
Walk Through				
1. Adequate medical facilities, personnel, and equipment to:				
a) monitor protocol				
b) perform & record physical exams				
c) perform ECGs				
d) collect urine samples				

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Item	Yes	No	NA	Notes
e) draw blood				
f) dispose of hazardous waste				
g) transmit/send study data to node data center				
2. Centrifuge equipment available for use				
3. Refrigerated storage available for urine samples and other biological samples				
4. Storage areas available for:				Is locked file necessary for this section?
a) participant binders (locked file cabinets in secure, limited access area)				
b) medication (locked drug cabinet in secure, limited access area of clinic)				
c) audio and video tapes (locked file cabinet in secure, limited access area)				
d) other supplies				
5. Medication and other study-specific supplies on hand.				
6. Pharmacy and pharmacy staff prepared to receive, store, and dispense medication (if applicable)				
7. In-house laboratory staff, or contracted laboratory, prepared to receive and process samples from study staff and to return results.				

Comments/Notes

More comments possible. Delete rows to minimize pages.