Protocol Tasking Checklist

Task	Resources/comments														
	PI	CTP Dir	LI	NIDA Colla	Pro Mana	Node Coor	SC	CTP Rep	DD&AS	TSC	QAS	RAS	PRS	NIDA	
														PRB	CTN Unit
Select Lead Investigator							X								
Assign Project Team			X												
Approve Project Team							X								
Initiate regulatory documentation for IND			X		X	X						X			
Contact drug supplier to ensure availability			X												X
Initiate drug import permit documentation			X												X
Identify pharmacy receiving drug into US			X												X
Prepare plan for drug distribution			X		X	X						X			X
Draft Protocol and Consent			X	X					X				X		X
Select CTPs	X	X				X									
Conduct CTP assessment															
Perform site visits of potential sites	X	X				X					X				
Define the work to be performed	X	X				X									
Establish time frames	X	X				X									
Identify pharmacy	X	X				X					X				
Identify laboratory	X	X				X					X				
Confirm OPRR assurance	X	X				X						X			
Confirm DEA requirements are met	X	X				X						X			
Assure proper storage of drug & supplies	X	X				X					X				
Complete Assurance forms (CPA) for CTPs		X				X						X			X
Prepare Data Management Plan			X	X	X	X			X						X
Prepare Operation Manual (SOPs)			X	x	X	X		X							X
Prepare Training Plan			X	X	X	X		X		X					X
Prepare QA Plan			X		X	X		X			X				X
Design Case Report Form (CRF)			X		X				X						X
Establish Supply Plans					X	X									X
Prepare study budget draft	X	X			X	X									
Complete regulatory documents (FDA, DEA, etc)					X	X									
Assure proper licensing (pharmacy, lab, etc)					X	X					X				
Review Protocol and consent															
Protocol Team (including subc. Members)								X	X	X	X	X	X		X
Steering Committee							X								
Incorporate comments			X										X		X
Finalize Protocol and Consent			X										X		X
Arrange protocol review by:															
NIDA Protocol Review														X	X
IRBs						X						X			
RAP (CA state only)						X						X			
Obtain the Confidentiality Certificate					X	X									X
Incorporate Comments to the protocol			X		X								X		
Complete operation manual															
Data Management									X						
Operations manual (all sections)					X										
Operational Training (i.e. GCP)					X					X					
Regulatory issues & confidentiality												X			
QA (including monitoring)											X				
QA (Therapy)			X			X					X				
CRF									X						
Investigator Brochure			X												
Supplies															X
Therapy Manual (Behavioral Protocols)			X	X						X					
Identify trainer(s)	X					X									
Set up database						X			X						
Obtain IRB Approval of Protocol, Consent, etc.					X	X						X			
Complete study budget	X		X												
Compile & ship trial materials					X	X									X
Coordinate pre-implementation meeting			X		X										X
Protocol implementation kick-off meeting															X
Ship Protocol & Manuals to sites															X
Start Training at Sites					X	X				Trainer					
Work to be performed						X				Trainer					
Drug storage, handling, labeling, etc.						X				Trainer					
QA of study						X				Trainer					
Data collection						X				Trainer					
Inv. Brochure						X				Trainer					
Regulatory & documentation issues						X				Trainer					
Therapy Training (Behavioral protocols)			X			X				Trainer					
Begin Study Enrollment															

Definitions:

PI=Principal Investigator
DD&AS=Data Design & Analysis Subcommittee
RAS=Regulatory Affairs Subcommittee
LI=Protocol Lead Investigator
TSC=Training Subcommittee
PRS=Protocol Review Subcommittee
SC=Steering Committee
QAS=Quality Assurance Subcommittee