

NODE PROTOCOL PRE-INITIATION WORKSHEET (V7 – 17 Feb 2004)

Protocol#: CTN-_____ **Protocol Name:** _____

Protocol Type (circle one): **BEH** **MED** **COMB** **OTHER**

Node: _____

Date: _____ **Completed by (name):** _____

Item	Yes	No	NA	Notes
Receipt of the following from Lead Node				
Complete Protocol & Documents				
a. Final Protocol and amendments				
b. CRFs				
c. Sample Informed Consent Form				
d. Sample Budget				
e. Suggested Staffing				
f. Data Dictionary				
g. Operation Manual(s)				
h. Protocol Specific QA Plan				
i. Protocol Training Requirements & Plan				
j. Test Data				
k. Safety Monitoring plan (in protocol)				
l. Pharmacy Binder				
m. Investigational Brochure				
n. Other, specify				
Participating RRTC/Node				
1. Training				
a. Training requirements met as defined by the Lead Node and/or as established by the Training Subcommittee				
b. Plans made for conducting any remaining training required				
c. Plans made for conducting training of replacement personnel				
2. Quality Assurance (QA)				
a. Node QA plan (generic) developed				
b. Node enhancement of protocol-specific QA plan (e.g., node specific information is added)				
3. Node level IRB Approval obtained, if applicable				

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4. Node CRFs developed and distributed to CTP(s) (reproduced and organized into participant CRF binders, if appropriate)				
5. Node CRF Completion Instructions developed and distributed to CTP(s)				
6. Data Management				
a. Data management system developed, tested, and documented according to DMAS procedures (internal system validation)				
b. Node protocol-specific data monitoring plans developed i. Data Management Plan ii. Data QA Plan				
7. Test data				
a. Test Data processed according to node's standard procedures				
b. IMC accepted data feed and documents no problems encountered (external system validation)				
c. Data center has received NIDA data system certification				
8. Node data center ready to process protocol data				

Comments/Notes
