

**NODE PROTOCOL PRE-INITIATION WORKSHEET (V5 - 06 July 2001)**

**Protocol#:** CTN-\_\_\_\_\_ **Protocol Name:** \_\_\_\_\_

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

**Node:** \_\_\_\_\_

**Date:** \_\_\_\_\_                      **Completed by (name):** \_\_\_\_\_

Item	Yes	No	NA	Notes
<b>Receipt of the following from Lead Node</b>				
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)				Still to be determined
l. Other, specify				
<b>Participating RRTC/Node</b>				
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				
4. Node CRFs developed and distributed to CTP(s) (reproduced and organized				



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