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

Protocol#: CTN	_Protocol Name:			
Protocol Type (circle one):	BEH	MED	COMB	OTHER
Node:				
Date:	Comp	leted by (1	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				Still to be determined
protocol)				
1. 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				
4. Node CRFs developed and distributed				
to CTP(s) (reproduced and organized				

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Node:				
Date:	Comp	leted by (na	me):	

	Item	Yes	No	NA	Notes
	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				NOTE: DMAS working on checklist
	a. Test Data processed according to node s standard procedures				
	b. IMC accepted data feed and documents no problems encountered (external system validation)				
	c. Lead Node verified data sent was accurate and correct				
8.	Node data center ready to process protocol data				

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