

CNDR Research Proposal Submission Form

Version 1.0 July 12, 2010

Research Proposal Title:				
Sponsor(s):				
Principal Investigator:				
Contact Information:	Phone:			
	Email:			
Mailing Address:				
All other Investigators				
Date of Submission to CNDR:				
Submission Timeline:	4 weeks or less (Expedited review)	2 months	3-6 months	+6 months
Has your study obtained ethics approval at the institution of the principal investigator?			Yes	No
If you answered No to the above question what is the expected date of decision?				
What are the inclusion criteria for the study?				
What are the exclusion criteria for the study?				
How many subjects total is the study looking for?		Adult	Pediatric	
How many subjects are currently enrolled?		Adult	Pediatric	
What are the desired regions for recruited subjects?				



What, if any criteria, are there for study sites?	
Please give a brief synopsis of the study (maximum 3 pages):	



Please give a brief description of risks to the participants of the study:			
Has appropriate insurance been obtained?	Yes	No	N/A
Is there a Data Safety Monitoring Committee in place	Yes	No	N/A
Is there monetary compensation for study subjects?	Yes		No
Have any adverse events occurred in the trial to date?	Yes		No
Does this study involve collection of tissue/fluid samples?	Yes		No

Attachments (check off all included items)

Copy of Letter of Approval from Ethics Review Board OR

Copy of Ethics Submission

Copy of Investigator's Brochure for Trial/Study if applicable

Copy of Research Study Protocol

Copy of Consent Forms/Withdrawal Forms as applicable

Study Budget

Proof of Study Funding (e.g. Letter of Commitment)

Applicable Regulatory Documents

Principal Investigator CV

Adverse Event Reporting (if any exists)

Copy of Previous Peer Review if available (must be included if expedited review is requested)