Questionnaire to Sponsor

Topic	Questions	Sponsor Response
Timeline	When does the sponsor anticipate enrollment to end? What is the trigger for the end of enrollment?	
	When does the sponsor anticipate the last patient will complete the study?	
	What is the anticipated date of study closure?	
Monitoring Plan- Monitoring SOP	How often will monitor visits take place?	
	How many days is the monitor on site?	
	Will CRA be required to check in with study staff? How often?	
	Are visits expected to be onsite or remote?	
	Will monitoring require 100% source data verification (SDV) or will risk-based monitoring (RBM) be applied?	
Study Team Meetings	Does the sponsor/CRO hold regular meetings? How often?	
	What study staff are required to attend the meetings?	
Pre-screening	Does the sponsor require a prescreening log to be submitted?	
	How often does the sponsor expect to receive prescreening logs?	
Retention	Does the sponsor request check in calls to retain subjects that are not captured in the visit schedule?	

	Does the sponsor have a required number of calls for lost to follow up patients?	
Data Entry, Lock and Queries- Data Entry SOP	How many days do study personnel have to enter data?	
	How much notice will the sponsor give the site before data lock?	
	Is it possible notice will be less than 48 hours?	
	What is the sponsor's data query resolution expectation?	
Payment Terms	How often are participant milestone payments made?	
	Will participant milestone payments require invoicing, or will they be auto paid based on EDC entries?	
	Is there a platform for submitting invoices, or are submissions made directly via email?	
	A detailed payment report will be required for all payments. How will the sponsor provide the report?	
	Can the sponsor agree to the Start Up fee being paid at CRADA execution?	
Study Coordinator effort	Can copy of eCRFs be provided for review, to assess the time/effort required for data collection and eCRF completion.	
	Can Lab Manual be provided for review, to assess lab processing requirements and required time/effort.	
	Will source documents be provided by Sponsor?	
Additional Study costs	If central labs are being shipped: Will there be a courier? Will the site need to provide dry ice? What supplies will be provided to the site for shipping?	

	Will the sponsor or site manage patient payments? Are both visit stipend and travel reimbursement available?	
	Is there an allowance for refreshments provided during in-service meetings?	
	Does the budget include payments for screen failures? Is it consistent with the procedures done prior to screen failure?	
Study Drug	How is study drug provided to site?	