

VAMHCE RESEARCH SERVICE GUIDELINE
Pre-Study Assignment of Responsibilities - Sponsor

PRE-STUDY INVESTIGATOR-SPONSOR-STAFF MEETING(S)
AGREEMENT ON ISSUES, ASSIGNMENT OF RESPONSIBILITIES, POINTS FOR FOLLOW-UP

DATE: _____ MEETING ___ OF ___ STUDY: _____

PARTICIPANTS: _____

	UNIT Responsibility	Investigator Responsibility	Sponsor Responsibility
IRB submission		X	
IRB amendments			
IRB reports: annual			
IRB reports: SAE			
Notification of other party of IRB approvals & amendments			
Regulatory Docs file			
Time-Event Sheet	X	Accept? Y / N Wants input into revisions? Y / N	
Design of DCF's (source documents): Screening			
Enrolled			
Maintenance of DCF's (source documents): Screening			
Enrolled			
Recruitment activities (specify if responsibilities are split)			
Screening activities (specify if responsibilities are split)			
Enrolled activities (specify if responsibilities are split)			
Registration			
Admission			
Scheduling: sbjts			

VAMHCE RESEARCH SERVICE GUIDELINE
Pre-Study Assignment of Responsibilities - Sponsor

	Unit Responsibility	Investigator Responsibility	Sponsor Responsibility
Scheduling: staff			
Contact forms			
MD coverage			
Supervision of staff			
Coordinator			
Phlebotomy			
Shipping samples			
Storing samples			
Other activity:			
Other activity:			
Acquiring equipment			
Returning (shipping) loaned equipment			
Training on new equipment			
Clerical (significant amounts of FAXing, xeroxing, mailings, etc)			
QA			
Transcription to CRF's			
Monitor visits: CRF's			
Monitor visits: Reg Docs			
Notifying Sponsor of SAE's			
Other items:			

Other items:

Question	Answer
PI allows contact with Sponsor?	Contact person(s):
PI allows direct budget with Sponsor for CRU portion?	Contact person(s):

VAMHCE RESEARCH SERVICE GUIDELINE
Pre-Study Assignment of Responsibilities - Sponsor

How many destinations for shipped samples?	
How many shipments per sbjt/visit/etc?	
How much notice before an admission?	
Likelihood of cancellations/postponements	
Financial arrangement for cancellations:	
Financial arrangement for postponements:	
What equipment needs to be obtained?	
CRU space needed? (cross-out those not needed; specify amount, etc of those needed)	Offices, exam rooms, inpatient rooms, storage space, other: _____
CRU equipment needed? (cross-out those not needed; specify amount, etc of those needed)	Refrigerators, freezers, centrifuges, telephone lines, computers, special equipment: _____; other: _____
CRU personnel needed? (cross-out those not needed; specify amount, etc of those needed)	RN's, PCA's, phlebotomists, screeners, recruiters, data managers, chart reviewers, NP's, other _____
CRU rep to Investigator Meeting? (significant CRU role only)	
Acknowledgement of CRU in publications	
Sponsor must know that CRU is an entity independent of PI	
Other providers of services which the CRU will work with / coordinate, etc?	Names & #'s:
Other:	

We understand and agree with the items as outlined on the preceding pages. We accept the above responsibilities.

Investigator: _____ Date: _____

Unit Representative: _____ Date: _____ Role: _____

Sponsor Representative: _____ Date: _____ Role: _____

Coordinator(s): _____ Date: _____