Routine Site Visit Report

General Information: Principal Investigator:

First Name:	Last Name:

Study Information:

Study Title:	IRB Study #:

Site Visit Date

Research Staff Present:

QIU Site Reviewer:

Visit Summary:

Strengths: **Education:** **Feedback for HRPP:**

Overall Summary Evaluation of Visit:

Satisfactory, No QIU Recommendations	
Satisfactory with Recommendations	
Significant Findings (Comment and IRB Follow-up Required)	

Research Staff Roles and Responsibilities:

Question	YES	NO
a). Have all key study personnel completed CITI training?		
b). Is there documentation of delegation of research activities?		
c). Other comments?		

B. Protocol Implementation: Subject recruitment, screening/enrollment process and records:

Question	YES	NO
a). Are recruitment activities per protocol?		
b). Are screening/ enrollment logs complete and up-to-date?		
c). Are subject withdrawals and dropouts documented?		
d). Are entry criteria documented and eligibility confirmed?		
e). Other comments?		

Informed consent process, records, and documentation:

Question	YES	NO
a). Does the informed consent document (ICD) accurately reflect the study protocol?		
b). Is the consent process being implemented per protocol?		
c). Are appropriate personnel conducting the consent process?		
d). Is the consent process adequately documented for each participant in the medical record/ research chart?		
e). Is a signed/dated copy of the ICD on file for each person screened or enrolled?		
f). Is a signed/dated copy of the HIPAA authorization on file for each person screened/enrolled (as applicable)?		
g). Is documentation on file that the Experimental Subject's Bill of Rights was provided (as applicable)?		
h). Is documentation on file that consent process was ongoing (as applicable)?		
i). Does the participant's MR include a signed copy of the ICD?		
j). Is the correct ICD version being used?		
k). Other comments on ICD audit/IC process, records, documentations?		

Section B. 2. comments:

Protocol adherence:

Question	YES	NO
a). Are all study procedures being conducted according to the IRB-approved protocol?		
b). Do reviewed CRFs demonstrate adherence to the approved IRB-approved protocol?		
c). Other comments on CRF audit/protocol adherence?		

Record retention and data storage:

Question	YES	NO
a). Is management of on-site research records conducted according to IRB-approved protocol?		
b). Is management of on-site electronic research data conducted according to IRB-approved protocol?		
c). Are desktop computers used for study activity encrypted?		
d). Are laptop computers and mobile devices used for study activity encrypted?		
e). Other comments?		

Section B. 4. comments:

C. IRB Post-Approval Communication:

Question	YES	NO
a). Were there any lapses in approval?		
b). Did any research activity occur during approval lapse?		
c). Were all modifications approved by the IRB prior to implementation?		
d). Other comments?		

D. Post-approval event reporting – adverse events (AE), violations, or incident reporting:

Question	YES	NO
a). Is there a process in place to capture and document all occurrences?		
b). Were adverse event reports submitted to the IRB per HRPP guidelines?		
c). Were incident or violations reported to the IRB per HRPP guidelines?		
d). Other comments?		

Section D. comments:

E. Regulatory Review:

Question	YES	NO
a). Do study files include all sponsor/FDA/NIH correspondence (as applicable)?		
b). Are drug/device accountability records complete (as applicable)?		
c). Other comments?		

Sponsor:

Federally Funded	
Other	
Industry	
Not Funded	

Study Characteristics:

Question	YES	NO
Investigator Initiated		
Investigator-held IND/IDE		
CTSI CRS		

CTSI CRS Involvement:

Question	YES	NO
Were all adverse events and/or protocol violations/incident reports reported to the PI?		

Research Site:

Parnassus	
Mt. Zion	
China Basin	
VAMC	
SFGH	
UCSF Affiliate	
Mission Bay	
Other	