Routine Site Visit Report

Principal Investigator	
First Name:	
Last Name:	

Study Information:	
Study Title:	
IRB Study #:	
Study Visit Date	

Personnel:	
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:	**Yes**	**No**
a) Have all key study personnel completed CITI training?	☐	☐
b) Is there documentation of delegation of research activities?	☐	☐
c) Other comments?	☐	☐

Sponsor:	
Federally Funded	
Other	
Industry	
Not Funded	

Regulatory Review:	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:	Yes	No
a) Investigator Initiated?	☐	☐
b) Investigator-held IND/IDE	☐	☐
c) CTSI CRS	☐	☐

CTSI CRS Involvement:	Yes	No
a) Were all adverse events and/or protocol violations/incident reports reported to the PI?	☐	☐

Research Site:	
Parnassus	☐
Mount Zion	☐
China Basin	☐
VAMC	☐
SFGH	☐
UCSF Affiliate	☐
Mission Bay	☐
Other	☐

Section A

1. Protocol Implementation: Subject recruitment, screening/enrollment process and records:	**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?	☐	☐

2. Informed consent process, records, and documentation:	**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?	☐	☐

3. Protocol adherence:	**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?	☐	☐

4. Record retention and data storage:	**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 A comments:

Section B

1. IRB Post-Approval Communication	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?	☐	☐

Section B comments:

Section C

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