Sample Template:
Documentation of the Informed Consent Process for On-Site Subject File

IRB#: _____

IRB Approval Date: _____

IRB Expiration Date: _____

Study Title: _____

PI: _____

Subject ID: _____

Consent obtained by: _____

Date of Consent: _____

Check all that apply	
☐	The subject meets all eligibility requirements.
☐	Was the subject's comprehension assessed to ensure that the subject understands the research and the risks and benefits involved in the study?
☐	Subject was given a copy of the California Experimental Subjects' Bill of Rights.
☐	Subject signed the UC HIPAA Research Authorization for Release of Personal Health Information for Research.
☐	Discussed, explained and reviewed the consent form with subject. ❑ Written consent was obtained (per IRB approved consent process) ❑ Surrogate consent was obtained (per IRB approved consent process)
☐	All of the subject's questions were answered/concerns addressed. (document multiple subject contacts below) ❑ Subject did not have any questions/concerns
☐	Subject was given time to review the consent form and to discuss participation in this study with family members/others.
☐	The subject has agreed to participate in the study and signed/dated the most current valid IRB approved consent form *prior to the start of any study procedures*.
☐	A copy of the signed and dated consent form was given to the subject.
☐	The original signed and dated consent form was placed in the research record or separate binder.
☐	Was there early withdrawal from research participation? If yes, note reason.

Signature/initials:	Date: