CRITERIA REQUIRED BY FEDERAL REGULATION TO APPROVE INFORMED CONSENT

1. GENERAL REQUIREMENTS		yes	not	n/a
a.	Information is in **language understandable** to participants or representatives	☐	☐	
b.	There is ***no exculpatory language*** through which participants or representatives are made to: • Waive or appear to waive any legal rights ***or*** • Release or appear to release the investigator, the sponsor, the institution or its agents from liability for negligence	☐	☐	

2. BASIC REQUIRED ELEMENTS		yes	no	n/a
a.	Statement that the ***study involves research***	☐	☐	
b.	Explanation of the ***purpose(s) of the research***	☐	☐	
c.	Expected ***duration*** of the participant's participation	☐	☐	
d.	Description of the ***procedures*** to be followed	☐	☐	
e.	Identification of any ***procedures which are experimental***	☐	☐	☐
f.	Description of any ***reasonably foreseeable risks or discomforts*** to the participant	☐	☐	
g.	Description of any ***benefits*** to the participant or to others which may reasonably be expected from the research	☐	☐	
h.	Disclosure of appropriate ***alternative procedures or courses of treatment***, if any, that might be advantageous to the participant	☐	☐	☐
i.	Statement describing the extent, if any, to which ***confidentiality of records*** identifying the participant will be maintained. *If study is FDA-regulated*, add statement that FDA may inspect the records.	☐	☐	
j.	*If research poses greater than minimal risk*, information on availability and nature of ***compensation or medical treatment available if injury occurs***	☐	☐	☐
k.	An explanation of whom to ***contact in the event of a research-related injury*** to the participant	☐	☐	☐
l.	***Contact information for the research team*** for questions, concerns, or complaints	☐	☐	
m.	***Contact information for someone independent of the research team*** for questions, concerns, problems, or input and for answers to pertinent questions about the research participant's rights.	☐	☐	
n.	Statement that ***participation is voluntary***	☐	☐	
o.	Statement that ***participant may refuse or discontinue participation*** at any time with no penalty or loss of benefits to which the participant is otherwise entitled	☐	☐	

Continue on other side…

CRITERIA REQUIRED BY FEDERAL REGULATION TO APPROVE INFORMED CONSENT--continued

3. ADDITIONAL ELEMENTS (WHEN APPROPRIATE)		yes	no	n/a
a.	The ***approximate number of participants*** involved in the study	☐	☐	☐
b.	A statement that the particular treatment or procedure may involve ***risks to the participant*** (or to the embryo or fetus, if the participant is or may become pregnant) which are ***currently unforeseeable***	☐	☐	☐
c.	Statement that ***significant findings*** during the course of the research which may relate to participant's willingness to continue participating ***will be provided to the participant***	☐	☐	☐
d.	Anticipated circumstances under which ***PI may terminate participation*** without participant's consent	☐	☐	☐
e.	***Consequences of a participant's decision to withdraw*** from the study	☐	☐	☐
f.	***Procedures for orderly termination*** of participation by the participant	☐	☐	☐
g.	Any ***additional costs*** to the participant that may result from research participation	☐	☐	☐
h.	The ***amount and schedule of payments*** to the participants	☐	☐	☐

4. OTHER REQUIREMENTS (STATE LAW, UNIVERSITY POLICY)		yes	no	n/a
a.	Disclosure statement that informs participants that investigator(s) may have ***a conflict of interest*** (financial interests and/or dual physician-research roles)	☐	☐	☐
b.	*If the study has a real or foreseeable risk of biomedical harm*, statement that participants will be given a copy of the consent form and ***a copy of the Experimental Subject's Bill of Rights*** in participants' own language to keep	☐	☐	☐
c.	***Required UCSF boilerplate sections*** for tissue/blood samples, establishment of cell lines, genetic testing	☐	☐	☐