

# CRITERIA REQUIRED BY FEDERAL REGULATION TO APPROVE INFORMED CONSENT

1. GENERAL REQUIREMENTS		yes	not	n/a
a.	Information is in <b>language understandable</b> to participants or representatives	<input type="checkbox"/>	<input type="checkbox"/>	
b.	There is <b>no exculpatory language</b> through which participants or representatives are made to: <ul style="list-style-type: none"> <li>• Waive or appear to waive any legal rights <b>or</b></li> <li>• Release or appear to release the investigator, the sponsor, the institution or its agents from liability for negligence</li> </ul>	<input type="checkbox"/>	<input type="checkbox"/>	
2. BASIC REQUIRED ELEMENTS		yes	no	n/a
a.	Statement that the <b>study involves research</b>	<input type="checkbox"/>	<input type="checkbox"/>	
b.	Explanation of the <b>purpose(s) of the research</b>	<input type="checkbox"/>	<input type="checkbox"/>	
c.	Expected <b>duration</b> of the participant's participation	<input type="checkbox"/>	<input type="checkbox"/>	
d.	Description of the <b>procedures</b> to be followed	<input type="checkbox"/>	<input type="checkbox"/>	
e.	Identification of any <b>procedures which are experimental</b>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f.	Description of any <b>reasonably foreseeable risks or discomforts</b> to the participant	<input type="checkbox"/>	<input type="checkbox"/>	
g.	Description of any <b>benefits</b> to the participant or to others which may reasonably be expected from the research	<input type="checkbox"/>	<input type="checkbox"/>	
h.	Disclosure of appropriate <b>alternative procedures or courses of treatment</b> , if any, that might be advantageous to the participant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i.	Statement describing the extent, if any, to which <b>confidentiality of records</b> identifying the participant will be maintained. <i>If study is FDA-regulated, add statement that FDA may inspect the records.</i>	<input type="checkbox"/>	<input type="checkbox"/>	
j.	<i>If research poses greater than minimal risk, information on availability and nature of <b>compensation or medical treatment available if injury occurs</b></i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k.	An explanation of whom to <b>contact in the event of a research-related injury</b> to the participant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l.	<b>Contact information for the research team</b> for questions, concerns, or complaints	<input type="checkbox"/>	<input type="checkbox"/>	
m.	<b>Contact information for someone independent of the research team</b> for questions, concerns, problems, or input and for answers to pertinent questions about the research participant's rights.	<input type="checkbox"/>	<input type="checkbox"/>	
n.	Statement that <b>participation is voluntary</b>	<input type="checkbox"/>	<input type="checkbox"/>	
o.	Statement that <b>participant may refuse or discontinue participation</b> at any time with no penalty or loss of benefits to which the participant is otherwise entitled	<input type="checkbox"/>	<input type="checkbox"/>	

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

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

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