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	Key information summary (required only for studies reviewed under the 2018 common rule and over 4 pages)	☐	☐	☐
b	Statement that the ***study involves research***	☐	☐	
c	Explanation of the ***purpose(s) of the research***	☐	☐	
d	Expected ***duration*** of the participant's participation	☐	☐	
e	Description of the ***procedures*** to be followed	☐	☐	
f.	Identification of any ***procedures which are experimental***	☐	☐	☐
g	Description of any ***reasonably foreseeable risks or discomforts*** to the participant	☐	☐	
h	Description of any ***benefits*** to the participant or to others which may reasonably be expected from the research	☐	☐	
i.	Disclosure of appropriate ***alternative procedures or courses of treatment***, if any, that might be advantageous to the participant	☐	☐	☐
j.	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.	☐	☐	
k	*If research poses greater than minimal risk*, information on availability and nature of ***compensation or medical treatment available if injury occurs***	☐	☐	☐
l.	An explanation of whom to ***contact in the event of a research-related injury*** to the participant	☐	☐	☐
m	***Contact information for the research team*** for questions, concerns, or complaints	☐	☐	

n	***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.	☐	☐	
o	Statement that ***participation is voluntary***	☐	☐	
p	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	☐	☐	
q	Statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent; or Statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies	☐	☐	☐

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	☐	☐	☐
i.	Statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit	☐	☐	☐
j.	Statement regarding whether clinically relevant research results, including individual research results, will be	☐	☐	☐

	disclosed to subjects, and if so, under what conditions			
k.	For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing	☐	☐	☐

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	☐	☐	☐