**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** |
|  | Statement that the ***study involves research*** | [ ]  | [ ]  |  |
|  | Explanation of the ***purpose(s) of the research*** | [ ]  | [ ]  |  |
|  | Expected ***duration*** of the participant's participation | [ ]  | [ ]  |  |
|  | Description of the ***procedures*** to be followed | [ ]  | [ ]  |  |
|  | Identification of any ***procedures which are experimental*** | [ ]  | [ ]  | [ ]  |
|  | Description of any ***reasonably foreseeable risks or discomforts*** to the participant | [ ]  | [ ]  |  |
|  | Description of any ***benefits*** to the participant or to others which may reasonably be expected from the research | [ ]  | [ ]  |  |
|  | Disclosure of appropriate ***alternative procedures or courses of treatment***, if any, that might be advantageous to the participant | [ ]  | [ ]  | [ ]  |
|  | 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. | [ ]  | [ ]  |  |
|  | *If research poses greater than minimal risk*, information on availability and nature of ***compensation or medical treatment available if injury occurs***  | [ ]  | [ ]  | [ ]  |
|  | An explanation of whom to ***contact in the event of a research-related injury*** to the participant | [ ]  | [ ]  | [ ]  |
|  | ***Contact information for the research team*** for questions, concerns, or complaints  | [ ]  | [ ]  |  |
|  | ***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. | [ ]  | [ ]  |  |
|  | Statement that ***participation is voluntary*** | [ ]  | [ ]  |  |
|  | 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** |
|  | The ***approximate number of participants*** involved in the study | [ ]  | [ ]  | [ ]  |
|  | 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***  | [ ]  | [ ]  | [ ]  |
|  | 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*** | [ ]  | [ ]  | [ ]  |
|  | Anticipated circumstances under which ***PI may terminate participation*** without participant’s consent | [ ]  | [ ]  | [ ]  |
|  | ***Consequences of a participant’s decision to withdraw*** from the study | [ ]  | [ ]  | [ ]  |
|  | ***Procedures for orderly termination*** of participation by the participant | [ ]  | [ ]  | [ ]  |
|  | Any ***additional costs*** to the participant that may result from research participation | [ ]  | [ ]  |  [ ]  |
|  | The ***amount and schedule of payments*** to the participants | [ ]  | [ ]  |  [ ]  |

|  |  |  |  |
| --- | --- | --- | --- |
| **4. OTHER REQUIREMENTS (STATE LAW, UNIVERSITY POLICY)** | **yes** | **no** | **n/a** |
|  | Disclosure statement that informs participants that investigator(s) may have ***a conflict of interest*** (financial interests and/or dual physician-research roles) | [ ]  | [ ]  | [ ]  |
|  | *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  | [ ]  | [ ]  |  [ ]  |
|  | ***Required UCLA boilerplate sections*** for tissue/blood samples, establishment of cell lines, genetic testing | [ ]  | [ ]  | [ ]  |