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

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| **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 |  |  |  |

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| **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 |  |  |  |

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

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| **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 |  |  |  |

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| **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 |  |  |  |