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| Stanford University<br><b>HRPP</b> | <b>Stanford required consent language for sIRB</b> | AID-03C057<br>1/3 |
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| ICF Element                                                                                                        | Text/Language in the ICF                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Instructions/Notes                                                                                                                                                                                                                                                                                                                                                                                                                |
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| <input type="checkbox"/> HIPAA Authorization                                                                       | <p>HIPAA Authorization must be embedded in the ICF</p> <p><i>Refer to the current version of the Medical Consent template for the required language</i></p> <p><a href="http://humansubjects.stanford.edu/consents/SUSampCons_CA_privacy.doc">http://humansubjects.stanford.edu/consents/SUSampCons_CA_privacy.doc</a></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <p>Even If the model consent includes HIPAA language, Stanford’s template HIPPA language should be used instead for participants at Stanford. The Authorization Form must appear in 14 point font and include its own signature block in order to comply with CA state regulations. CA law also requires a definite expiration date, although there are some exceptions to this requirement (e.g., for repository protocols).</p> |
| <input type="checkbox"/> Costs<br><input type="checkbox"/> Paragraph 1<br><br><input type="checkbox"/> Paragraph 2 | <p><i>[Include the following if there is no treatment involved and there will be no additional costs to the participant due to their participation in the research:]</i></p> <p>There is no cost to you for participating in this study, other than basic expenses like transportation and the personal time it will take to come to all of the study visits.</p> <p><b>OR</b></p> <p><i>[Include the following paragraphs if there might be additional costs to the participant due to their participation in the research:]</i></p> <p>If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the study that are not a part of your routine medical care. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the study visits. You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. You will also be responsible for any co-payments and/or deductibles as required by your insurance. Participation in this study is not a substitute for health insurance.</p> <p><b>AND, if applicable</b></p> <p><i>[Include the following paragraph, when applicable:]</i></p> <p>The protocol director will obtain insurance authorization for treatments associated with this study prior to your participation.</p> | <p>Choose the appropriate option and include. If the model consent includes equivalent language, Stanford’s template language does not have to be used.</p>                                                                                                                                                                                                                                                                       |
| <input type="checkbox"/> Research-related Injury                                                                   | <p><b><u>OPTION 1</u></b></p> <p>All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <p>The informed consent form must include language on participant compensation in the event of a research-related injury. Choose one of the two options below</p>                                                                                                                                                                                                                                                                 |

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|  | <p>might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, care will be provided to you. You will <b>not</b> be responsible for any of these costs.</p> <p>If you receive Medicare benefits, and if the sponsor of this study pays for any study-related treatment, complications or injuries, personal information about you, your treatment, and your participation in this study will be provided to the sponsor, who is required by law to provide it to Medicare.</p> <p>You do not waive any liability rights for personal injury by signing this form.</p> <p><b><u>OPTION 2</u></b><br/>All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. <b>You will be responsible for any associated co-payments or deductibles as required by your insurance.</b></p> <p>If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.</p> <p>You do not waive any liability rights for personal injury by signing this form</p> | <p>depending on the funding for the project. <b>No changes or additions are permitted to this language.</b></p> <p><b><u>Industry Sponsored Projects (Clinical Trials)</u></b><br/>Use <b>OPTION 1</b> if the Industry Sponsor <b>is</b> paying for medical care costs incurred as a result of research-related injury (adverse events):</p> <p>Note: Before submitting the consent form to the IRB, determine if the industry sponsor is paying for medical care costs incurred as a result of research-related injury. If you don't know, contact the contract officer (at the Office of Sponsored Research).</p> <p><b><u>Other Funding or No funding</u></b><br/>Use <b>OPTION 2</b> for:</p> <ul style="list-style-type: none"> <li>A. Projects with federal funding (i.e., NIH funding), Stanford Departmental funding, gift funding, medical scholars funding and projects with no funding.</li> <li>B. Industry funded projects when the Industry funder/sponsor <b>is not</b> paying for medical care costs incurred as a result of research-related injury. In these situations, the study must be reviewed and approved by the Spectrum Risk Assessment Committee (RAC). For information on RAC application, please contact your contract officer</li> </ul> |
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| <input type="checkbox"/> CA Bill of Rights | <p>As a research participant you have the following rights. These rights include but are not limited to the participant's right to:</p> <ul style="list-style-type: none"> <li>• be informed of the nature and purpose of the experiment;</li> <li>• be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;</li> <li>• be given a description of any attendant discomforts and risks reasonably to be expected;</li> <li>• be given an explanation of any benefits to the subject reasonably to be expected, if applicable;</li> <li>• be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;</li> <li>• be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;</li> <li>• be given an opportunity to ask questions concerning the experiment or the procedures involved;</li> <li>• be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;</li> <li>• be given a copy of the signed and dated consent form; and</li> <li>• be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.</li> </ul> | <p>This must be included <b>verbatim</b></p> |
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