**Refer to the IRB of record for the appropriate ICF template.**

|  |
| --- |
| **Subject Injury Language****The following language is OSF-required and must not be altered without prior written approval from OSF Research Administration and the IRB of Record.** |
| **1.** *When SPONSOR is paying costs for illness and/or injury, use:* |
| It is important for you to follow the study doctor’s instructions.  If you become ill or injured while you are in the study, contact the study doctor right away. Medical treatment will be provided at no cost to you and paid for by the sponsor of the study for study-related injuries. Study-related injuries are injuries caused by the product or procedures required by the study which you would not have experienced if you had not been in the study. You will not be paid for any other costs, such as lost wages.  You, or your medical insurance, will be responsible for other medical expenses resulting from your medical condition. You do not give up any of your legal rights by being in the study, and you may choose to pursue legal action if you are injured while you are in the study.  |
| **2.** *When SPONSOR is NOT paying costs for illness and/or injury, use:* |
| It is important for you to follow the study doctor’s instructions.  If you become ill or injured while you are in the study, contact the study doctor right away. Medical treatment will be provided for study-related injuries. The costs of this medical treatment will be billed to you and/or your insurance. Study-related injuries are injuries caused by the product or procedures required by the study which you would not have experienced if you had not been in the study. You will not be paid for any other costs, such as lost wages.  You do not give up any of your legal rights by being in the study, and you may choose to pursue legal action if you are injured while you are in the study. |
| **Pregnancy Language** |
| My physician has explained that this research may be hazardous to an unborn child. If I become pregnant while undergoing this research treatment/therapy, there may be injury to my baby. It is understood that by my agreement to participate in the clinical trial I will use acceptable means to avoid pregnancy throughout the duration of the study.Infertility is a [rare but serious] risk of specific [drugs, medical devices, or procedures] used in this study. Before taking part in the study, participants may wish to discuss with the researcher or their physician acceptable means of being able to have children in the future.  |

|  |
| --- |
| **Subject Payment Language** |
| You may receive compensation for your participation in this study. Compensation is a payment for your time and effort, approved by the IRB to ensure it does not unduly influence your decision to participate.  Your study doctor or coordinator will explain the payment details.  If you receive $600 or more from OSF in a year, then OSF must report this to the IRS and to you using a 1099 Form. No taxes will be withheld from your payment. You are responsible for reporting this income and paying any taxes owed, even if you are not a US citizen. Failure to do so may have financial and legal consequences. Total taxes owed are based on your annual income, which could include payments from other research studies. Contact the IRS or a tax consultant for more information on filing or paying taxes. Receiving compensation is OPTIONAL. If you choose to receive compensation, then you must provide additional information by filling out a form called a "Substitute W-9." OSF will use this form to track payments you receive from OSF and report your payments to the IRS ONLY IF your total payments from OSF for a year are $600 or more. The study team will explain and help you complete the form. If you choose to complete the form, thenthe study team and OSF will protect your information using many of the same ways they protect your health information. You have the right to refuse/decline to fill out the W-9 form to receive compensation payment(s). If you refuse, then OSF cannot pay you for your participation in the study. However, your refusal to complete the form and receive compensation payment does NOT prevent you from participating in the study or from receiving reimbursement payments.YES: I will provide required W-9 form to receive study compensationNO: I decline to provide W-9 and decline payment for participationSubject's Initials\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Another form of payment you may receive is reimbursement. Reimbursement is when the study team pays you for costs you have paid for such things as travel (e.g., gas), food, and lodging (e.g., hotel room). You MUST provide receipts of your costs in order to receive reimbursement payments. IMPORTANT: Reimbursement payments are NOT taxable income. You do NOT have to report reimbursement payments when you file your taxes. You do NOT need to complete the W-9 form to receive reimbursement payments. |
| **Genetic Testing Language**Since genetic testing will be done during the treatment period, you should know there is a Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination if you have already been diagnosed with the genetic disease being tested.There is a risk that someone could get access to the genetic information we have stored about you. Genetic testing can create information about subjects’ and their families’ personal health risks and can cause or increase anxiety, and/or interfere with your ability to get insurance or a job, and can even lead to discrimination. Patterns of genetic variation also can be used by law enforcement agencies to identify a person or his/her blood relatives. There are laws against this kind of misuse, but they may not give full protection. There may be other unforeseen privacy risks. We believe the chance these things will happen is very small, but we cannot make guarantees. Your privacy and the confidentiality of your data are very important to us and we will make every effort to protect them.  |