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

|  |
| --- |
| **Subject Injury Language** |
| **1.** *Select either of these paragraphs depending on who is responsible for payment:* |
| If a “research related- injury” results from your participation in this research study, medical treatment will be provided at no cost to you and paid by the sponsor of the study. A “research related-injury” means injury caused by the product or procedures required by the research which you would not have experienced if you had not participated in the research study.  You, or your medical insurance, will be responsible for other medical expenses resulting from your medical condition.  |
| *-OR-* |
| If a “research related injury” results from your participation in this research study, medical treatment will be provided. The costs for all your medical treatment will be billed to you and/or your insurance.  A “research related-injury” means injury caused by the product or procedures required by the research which you would not have experienced if you had not participated in the research.   |
| **2.** *Add the following two paragraphs after the first paragraph selected above:* |
| It is important for you to follow your physician’s instructions including notifying your study physician as soon as you are able of any complication or injuries that you experience.  |
| You will not be paid for any other injury- or illness-related costs, such as lost wages.  You are not waiving any legal rights thereby freeing sponsor, Principal Investigator, or hospital of any malpractice, negligence, blame or guilt by participating in this study. If you have questions, please call \_\_\_\_\_. |
| **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** |
| How and when you will be paid will be explained to you by the Study Doctor or Study Coordinator.Your Social Security Number (SSN) or Taxpayer Identification Number (TIN) must be collected in order for OSF Healthcare System to issue payment to you. You may also need to provide your address if a check will be mailed to you.  I choose NOT to provide my Social Security Number (SSN) or Taxpayer Identification Number (TIN) and do NOT want to participate in this trial. I choose NOT to provide my Social Security Number (SSN) or Taxpayer Identification Number (TIN); however, I want to participate in this trial. I understand this willingly opts me out of receiving payment for participation in this trial.  I choose to provide my Social Security Number (SSN) or Taxpayer Identification Number (TIN) and want to participate in this trial. Research payments greater than or equal to $600.00 per year (or cash equivalent) are reported by OSF Healthcare System to the Internal Revenue Services for federal tax purposes. Your Social Security Number (SSN) or Taxpayer Identification Number (TIN) will be used for this purpose. Reimbursements for travel or per diem do not count toward this total. If you receive research payments totaling more than $600 per year a tax form 1099 will be issued by OSF Healthcare System and mailed to the address on file for you.[Clearly describe the monetary compensation:* total amount,
* average total amount,
* amount per visit,
* amount per hour, etc.]

[If compensation is pro-rated when a subject withdraws prior to completing the study, explain how it is pro-rated.][If there is non-monetary compensation (e.g., small gift, gift certificate), describe that separately from the monetary compensation statement.]Initials: \_\_\_\_\_\_\_\_\_ |
| **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.  |