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**To Whom It may Concern:**

As part of our commitment to ethical and transparent clinical research, we recognize the critical importance of subject injury language (SIL) in informed consent forms. SIL serves several key purposes:

1. **Explanation of Participant Rights**: SIL outlines what study participants should do if they believe they have been injured as a result of their participation in a study. It provides clear guidance on reporting procedures and ensures that participants are aware of their rights.
2. **Financial Responsibility**: SIL specifies who may bear the costs associated with healthcare and other expenses related to study-related injuries. This clarity is essential for both participants and researchers.
3. **Regulatory Compliance**: SIL aligns with regulatory requirements, ensuring that our informed consent process adheres to the highest ethical and regulatory standards (45CFR46 and 21CFR50).

**Basic Requirements for SIL:**

1. **Clarity and Accessibility**: SIL must be written in plain language, avoiding jargon or complex terminology. Participants should easily understand their rights and responsibilities.
2. **Inclusion in Informed Consent Form**: SIL should be prominently placed within the informed consent document. Participants must encounter it early in the consent process.

**Fixed Standard SIL**:

UNC-Chapel Hill maintains a fixed standard SIL that applies uniformly across all industry sponsored clinical trials. This standard language has been carefully crafted to meet regulatory expectations and protect participant rights. It is non-negotiable and remains consistent regardless of the industry sponsor.

UNC-Chapel Hill's SIL is broad enough to capture a majority of positions taken in a standard clinical trial agreement (CTA). UNC-Chapel Hill's standard SIL is as follows:

*If you think you have been injured because of taking part in this study, tell the study doctor or the contact on the front page of this document as soon as possible. You can provide this information in person or call them at the phone number listed in this consent form. The study doctor or someone on the study team can help you get the care you need. If you are injured because of this study, UNC will provide necessary medical treatment. You can also see another doctor for treatment, or if you have an urgent injury call 911.*

*The study sponsor [enter sponsor name] may pay for the cost of medical treatment for your injury. Your study doctor and the study sponsor will work together to determine what costs associated with your injury may be covered by the study sponsor.*

*If the study sponsor pays any part of the cost of medical treatment for your injury, the study sponsor will need to know information about you like your name, date of birth, and Medicare Beneficiary or social security number. This*

*information is needed because the study sponsor must check to see if you have health care insurance through Medicare. If you have Medicare, the study sponsor must report to Medicare the payment that has been made toward your medical expenses for the injury. The study team will not collect your Medicare Beneficiary or social security number unless you are injured and a claim is submitted to the study sponsor to pay medical expenses.*

*If the study sponsor does not pay, you will be responsible for all costs. Your insurance company may reimburse you for some costs. You will be responsible for deductibles, co-payments, and co-insurance for treatments that are billed to your insurance company. You should check with your insurance company about any such payments. Since this is a research study, some health insurance plans may not pay for any costs.*

*There are no plans to pay you directly or give you any other type of compensation should you be injured because of taking part in this study. However, signing this consent form does not mean you give up or otherwise waive your rights to seek payment for injuries arising from the study*.

**Clinical Trial Agreement (CTA) Negotiation Phase**:

While SIL, within the informed consent documentation, is fixed, we recognize that other aspects of clinical trial agreements (CTAs) require negotiation. Discussions related to responsibility for subject injury take place during the CTA negotiation phase which is handled by UNC's Office of Sponsored Programs. After a CTA is negotiated, UNC-Chapel Hill's Clinical Research Compliance Office is responsible for conducting a review to ensure CTA language and SIL language are congruent.

**Conclusion**:

By adhering to our standard SIL and emphasizing regulatory compliance, we prioritize participant safety and uphold the integrity of our research endeavors.

Thank you for your attention to this matter.

Sincerely,

Andy Johns
Senior Associate Vice Chancellor for Research