

Subject: Introducing Our New Subject Injury Language Process - Effective June 15, 2024

Dear Research Colleagues:

I hope this message finds you well. I am pleased to announce that UNC-Chapel Hill is adopting standardized subject injury language (SIL) for industry sponsored clinical trials to increase patient transparency and simplify the IRB approval process.

**Effective June 15, 2024, UNC-CH will no longer require a Subject Injury Approval Letter with the submission of the IRB application. Please see the language options at the end of this email.**

- If the UNC IRB will be the IRB of record, the injury language will automatically populate into the consent document when completing the IRBIS application.
- If you are relying on an external IRB, are submitting for reliance approval, and UNC is enrolling participants, please update the subject injury language in the model consent form with the approved language that is noted below.
- There will be no changes to approved “boilerplate language” previously agreed upon with NCI CIRB.
- If you have previously requested an SIL approval letter for an IRBIS submission that is currently in process and have not yet received it, please email [SIL@unc.edu](mailto:SIL@unc.edu) to let me know.

The updated language is posted on the OHRE website at [Sample Consent Forms - UNC Research](#) and the OHRE SOP 1601 will be updated to reflect this new process. Additionally, we will be posting the position statement and language options on the current OCT website ([OCT Website](#)) in the next few weeks.

***Subject Injury Language that has been previously approved does not require updating.***

Thank you for your contribution to advancing human subject research. **If you have questions, please email [SIL@unc.edu](mailto:SIL@unc.edu).**

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**OPTION A: Injury language when there is no industry sponsor:** investigator-initiated, Federally-funded (e.g. NIH), foundations, non-profit organization

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.

UNC at Chapel Hill (and/or the Study Sponsor – use if there is also an external sponsor) has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study-related injuries.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

**OPTION B: Injury language for industry sponsored studies.** This section cannot be modified without the approval of the Clinical Research Compliance Office (CRCO). Doing so may result in IRB approval delay. Contact CRCO at [SIL@unc.edu](mailto:SIL@unc.edu) if you have questions.

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.