

May 10, 2024

To Whom it May Concern:

This is to confirm that it is an institutional policy and practice of The Rector and Visitors of the University of Virginia (UVA) to use consistent subject injury language in informed consent with study subjects/participants. When the sponsor will be reimbursing study participant injury costs, only the language below may be used. Requests for other exceptions to this policy will only be considered in rare/exceptional circumstances, where the sponsor has provided a compelling reason for the exception, and only following consultation with the Office of University Counsel. Contractual terms and conditions as may be negotiated between UVA and the study sponsor will not be included in the consent language.

*You do not give up any legal rights, such as seeking compensation for injury, by signing this form.*

*If you get sick, have a medical complication, or are injured from being in the study, call the study doctor immediately (phone numbers are located near the end of this form). The doctor will either treat you or direct you to another doctor for treatment.*

*The study doctor and study sponsor will determine whether your condition was the result of being in the study. The sponsor will reimburse UVA the cost of treating your injury or illness only if it was caused by being in the study.*

*Injury from the study does not include the normal progression of any disease or any underlying pre-existing medical conditions. You or your health plan will have to pay for the costs of injury or illness not resulting from being in the study.*

*There are no plans to pay you for lost wages, disability, or discomfort if you are hurt from being in the study.*

*To reimburse UVA for medical expenses, the sponsor may need to know some information about you like your name, date of birth, gender, social security number, and, if you have health insurance coverage through Medicare, your Medicare Beneficiary Identifier (MBI). This is because the sponsor must check to see if you receive Medicare and if you do, report the payment it makes to Medicare. The sponsor will not use this information for any other purpose.*

*Contact the study team with any questions about what is covered for possible injuries from being in the study.*

Sincerely,

DocuSigned by:

*Kelly Hochstetler*

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Kelly Hochstetler, PhD

Associate Vice President for Research Operations, Compliance and Policy