

March 25, 2024

To Whom It May Concern:

This is to confirm that it is an institutional policy of The Rector and Visitors of the University of Virginia (UVA) that only the language below may be used for informed consent with study subjects/participants. Requests for 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 consent language.

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study, you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for lost wages, disability, or discomfort. The sponsor will reimburse the reasonable cost of necessary and appropriate emergency and/or acute medical care for injury or illness that is determined by the principal investigator and sponsor to be directly related to the study. Injury related to the study does not include the normal progression of any disease or any underlying pre-existing medical conditions.

To pay medical expenses, the sponsor will 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.

Sincerely,

DocuSigned by:

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Kelly Hochstetler

Associate Vice President for Research Operations, Compliance & Policy