Part 2 of 2: STUDY SITE INFORMATION

Site Name:	Saint Louis University
Site Principal Investigator:	[redacted]
Site Principal Investigator Contact:	[redacted]
Site Study Coordinator:	[redacted]
Site Study Coordinator Contact:	[redacted]

This part of the consent form includes information about the site that is asking you to participate in this study and is specific to participation at your site only. Before making your decision, both the site-specific information and the general study information should be reviewed with you. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Reproductive Risks:

Pregnancy/Woman of Childbearing Potential

If you are a woman of childbearing potential, please read and sign below.

Some research medications or procedures can cause severe birth defects, mental disability in an unborn baby, or loss of an unborn baby. If you take part in a research study that includes a drug or medical procedure, you must be willing to have a pregnancy test done before beginning your participation and you must avoid becoming pregnant while you take part in the research study.

If you are pregnant or breast feeding a baby, you cannot take part in this research study. If you become pregnant during the study you will not receive any further doses of study drug but will be followed for your safety if you agree. If you are pregnant or think you are pregnant, it is important for you to tell the study doctor immediately.

If you are sexually active during your participation in the research, you must use effective measures (chosen in consultation with your health care provider) to avoid becoming pregnant for 30 days prior to the first study vaccination through at least 60 days after the last study vaccination.

Your signature below indicates you agree to these requirements.

☐ Check this box if this section does not apply to you (no signature needed).

Signature and Date_____

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Genetic Information Nondiscrimination Act (GINA):
There is a possible risk that loss of confidentiality with regard to or misuse of genetic information could lead to discrimination against participants. The chance of this happening is remote. Importantly, a US Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate based on your genetic information. Under this law, health insurance companies and group health plans may not ask for genetic information obtained during this research study; health insurance companies and group health plans may not use genetic information when making decisions about eligibility for insurance or your premiums; and employers with 15 or more employees may not use your genetic information obtained during this research study when making decisions to hire, promote, or fire, or when setting the terms of employment. GINA, however, does NOT protect against discrimination by companies that sell life, disability, or long-term care insurance.

Payments for your time spent taking part in this study or expenses:
You will be compensated for your time and participation in this study. You will be paid $[redacted] for each required vaccination (1-2), $[redacted] for each clinic visit (6-12), and $[redacted] for each phone/email/text contact (1-4). Total is between $[redacted] to $[redacted] (depending on what Stage you are in) for completing all planned study visits. You will also be compensated $[redacted] if we ask you to come in for extra visits during the study because of symptoms that need to be assessed by study staff. If you are withdrawn from the study for any reason you will be compensated for all completed visits.

If you are participating in the optional leukapheresis study, you will receive additional compensation for your time and participation. You will be paid $[redacted] if we ask you to come in for additional screening procedures to see if you are eligible for leukapheresis and $[redacted] for the leukapheresis procedure visit. The total compensation is up to $[redacted] for completing all leukapheresis study visits. If you are withdrawn from the leukapheresis study for any reason you will still be compensated for all completed visits. Additional site-specific information regarding leukapheresis is detailed in the SSM Health Research Leukapheresis Collection Informed Consent Form which will be reviewed with you before the procedure.

Payments for taking part in this research study will be put onto a participant payment card. The participant payment card is managed by an external company. Your personal information, such as your name, date of birth and social security number will be shared with this company to put study payments onto the card. While the participant payment card is not a credit card, the company may use your information like a credit card company would. You should review the terms and conditions of the participant payment card when deciding whether to take part in this study.

If you are a Saint Louis University employee, you will be paid via a participant payment card. Note: student workers can only receive payment through the payroll system.

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To receive payment for participation in this research, you will be asked to provide your home address and social security number. If you receive $600 or more for participation in this research study, or a combination of studies at Saint Louis University in one tax year, you will be sent an IRS Form 1099 for tax purposes. If you are a Saint Louis University employee, the University will withhold income taxes on research payments in accordance with the IRS Federal Withholding Form W-4. Tax withholding will occur on a future paycheck.

Costs to you if you take part in this study:
There is no cost to you for taking part in this study.

Who to call for any questions or in case you are injured because you took part in this research study:
If you have any questions or concerns about this research study, or if you have any problems that occur from taking part in this research study, you may call the Principal Investigator Dr. [redacted] or the other study doctors and appropriate Vaccine Center personnel.

If you have questions, concerns or complaints about your rights as a research participant and would like to talk with someone not on the research team, please contact the Saint Louis University Institutional Review Board (IRB) at 314-977-7744 or irb@slu.edu.

If you believe that you have been injured as a result of your participation in the research study, please contact the research study doctor and/or the Chairperson of the Institutional Review Board.
You will receive necessary medical treatment in the event that an injury results because of your participation in this research. The University will have the right to determine whether an injury is related to your participation in this study or happened because of your medical condition or other reasons which are not related to this study. If the injury is due to participation in the research, you will not have to pay for the cost of this treatment unless your injury is due to your own failure to follow the study doctor's instructions. There are no plans for Saint Louis University to pay for the costs of any additional care. You have not waived your legal rights by signing this form. If you have any questions, please call the Saint Louis University General Counsel's office at 314-977-5767.

In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH or the Federal Government.

A Declaration under the Public Readiness and Emergency Preparedness (PREP) Act was issued by the Secretary of the United States Department of Health and Human Services on March 10, 2020. This Declaration limits the legal rights of a subject participating in clinical studies utilizing COVID-19 countermeasures, such as the vaccines used in this study. Because this study is covered by the Prep Act Declaration, covered persons, such as the manufacturers, study sponsor, researchers, healthcare providers and others have liability immunity (that is, they cannot be sued by you or your family under the laws of the United States).

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For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Medical Center Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Additional information about your local site:
You will receive an HIV test as part of this research. The result of your test may or may not become part of your medical record depending on where testing takes place. Per your request, the results of the HIV testing will be forwarded to your regular physician. As a volunteer in an approved research study, a confirmed positive HIV result will be reported to the Missouri Department of Health, but your identity will not be revealed.

In this study you will also receive a test for Hepatitis B and Hepatitis C. We may find out you have Hepatitis B/Hepatitis C and could spread the disease to others. If this occurs, a report to the Missouri Department of Health that includes your name is required.
Your participation in this research is voluntary. You may choose not to be a part of this research. There will be no penalty to you if you choose not to take part or withdraw. You may leave the research study at any time. The research study doctor or research study staff will let you know of any new information that may affect whether you want to continue to take part in the research study.

The study doctor or sponsor may decide to stop you from taking part in this study at any time, without your consent.

You could be removed from this study for any of the following reasons:

- Reasons related to you (for example, if you move to another city or do not agree to get your study drug).
- Reasons related to your health (for example, if you have a serious reaction to your study drug).
- Because this entire study is stopped (the sponsor may stop this study at any time).
- If you do not later consent to any future changes that may be made to how this study is done.
- Any other reason.

If you stop taking part in this study, we may ask you some questions about taking part in this study. To help you leave this study safely, we may ask you to take part in more tests.

Although the results from this study may be patentable or have commercial value, you will have no legal or financial interest in any commercial development resulting from the research.
The use of your samples and/or data may result in commercial profit, such as a product, material, or process. You will not be compensated for the use of your samples and/or data other than what is described in this consent form.

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Saint Louis University is receiving financial support from the NIH to assist in the conduct of this research study. The amount of payment is enough to cover the research study doctor's and/or institution's expenses to perform the research study.

Confidentiality and Privacy:
As a participant in this study, you will be asked to provide us with personal health information. Your individual study record will contain your photo identification, social security number, date of birth, information on how to contact you, and other information that could identify you personally. We will try to keep your personal health information confidential within the limits of the law. However, there is a chance that someone unauthorized will see your personal health information.

In order to maintain confidentiality, Dr. [redacted] and the other study doctors will keep your study record locked in a secure area; only the study team will have access and your electronic data will be stored on password protected computers on a secured network. Your reported study data and forwarded samples will not contain your personal identifiable information. The study data and forwarded samples will be labeled with an assigned code consisting of a unique number.

Only people who are involved in the conduct, oversight, or auditing of this study will be allowed access to the personal health information we collect. Any publications from this study will not use information that will identify you by name. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups, such as National Institute of Allergy and Infectious Diseases, the Food and Drug Administration, and the Institutional Review Board.

Saint Louis University officials and SSM Health St. Louis officials may review your research study records.

Your samples can only be traced to you by the study site and study staff allowed to do that. Your privacy will be kept to the extent allowed by law.

The program will keep a private record of your donation. Certain offices and people other than the researchers may look at your medical charts and study records. Government agencies (such as the U.S. Food and Drug Administration [FDA]) and study site employees overseeing proper study conduct may look at your study records. The study site will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

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Some information about your participation in this study will be kept in your medical record. Authorized Saint Louis University and Hospital staff have access to this information. Systems are in place to keep medical record information confidential. It is possible this information could be shared with insurance or healthcare providers who are authorized to have your medical records.

Your identifiable health information (information that contains anything that may be used to identify you) is protected by a federal law called Health Insurance Portability and Accountability Act of 1996 (HIPAA). You will be asked to review and sign and date a separate HIPAA authorization form that explains in greater detail exactly who will have access to your records; what health information about you may be reviewed and for what purpose; how long your permission for others to review and release your records will last; and how you may revoke (take back) your authorization if necessary.

Certificate of Confidentiality:
To help us protect your privacy, we have a Certificate of Confidentiality (Certificate) from the NIH. Study staff cannot provide or use your name, or any materials that contain identifiable information about you to any person not connected with the research, unless permitted by a legal exception, such as state laws that require reporting of some contagious diseases. The most important protection provided by the Certificate is that the study staff cannot be forced to provide any of your identifiable information in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, such as if there is a court subpoena, without your permission.

The study team will use the Certificate to resist any demands for information that would identify you. Your information protected by the Certificate may still be disclosed or used when the information:

1. is disclosed to people connected with the research; for example, information may be used for auditing or program evaluation internally by the NIH;
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the FDA. This does not include disclosure for use during legal proceedings as noted above;
3. is necessary for your medical treatment and you have consented to this disclosure;
4. is for other scientific research as allowed by applicable federal regulations; or
5. is disclosed with your consent.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing and dating below you consent to those disclosures.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly

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releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

Contact for Future Studies:
We may want to contact you in the future to see if you would like to participate in future studies. If and when you are contacted, you can decide if you want to participate in any of the other studies and you will sign another consent form to participate in those studies. Your decision regarding future contacts will not affect your participation in this study.

Please initial whether or not you give permission to be contacted regarding future studies:

_____YES, you may contact me about future studies.

_____NO, you may not contact me about future studies.

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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Date Signature of patient/volunteer

_____
Print Name

Consent obtained by:

_____ _____
Date Signature

_____ _____
Time Print Name and Title

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