STANFORD UNIVERSITY CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Please check one of the following:

_____ You are an adult participant in this study.

_____ You are the guardian granting permission for an adult in this study.

Print participant's name here:

_____

The following information applies to the adult participant or to the ward. If the participant is a ward, the use of "you" refers to "your ward."

Are you participating in any other research studies? _____ Yes _____No

PURPOSE OF RESEARCH

You are invited to participate in a research study examining vaccine responses as people age. We hope to discover new biological markers that will help us to predict whether a person is able to produce an effective immune response to the various types of vaccines as they age. The vaccines used in this study are licensed by the FDA and are not experimental.

Participants in this study will be followed over time to establish a long-term study of vaccine responses and general health. Identifying differences between older and younger participants and among individual participants over time may help to understand who is at highest risk for a poor immune response to the various vaccine types.

The vaccine types include seasonal flu vaccines and vaccines generally used when traveling abroad. Participants who are 18 to 40 years of age will receive Fluarix IIV4, a quadrivalent flu vaccine (designed to protect against four different flu viruses. Participants who are ages 65 and older will be randomized to receive either Fluzone High-dose IIV4, a quadrivalent flu vaccine (recommended for people in this age group) or Fluad IIV4, a quadrivalent flu vaccine (with an ingredient added to help the body produce a strong immune response).

The other vaccine that participants may receive in this study is for prevention of Hepatitis A. The Hepatitis A vaccine will be given twice during the 5-year study. The final study visit will consist of a single blood draw and the administration of a COVID-19 infection and vaccination questionnaire.

If you decide to terminate your participation in this study, you should notify the Stanford-LPCH Vaccine Program research staff at (650) 724-5551**.**

This long-term research study will be conducted at Stanford University. Up to 60, generally healthy adult participants will be enrolled from among participants previously enrolled in a separate longitudinal study or from prior participants in other Stanford vaccine studies. If we cannot enroll enough of the prior SLVP study participants we will supplement with new subjects who are otherwise healthy, ambulatory, and within the appropriate age group. The participants in this study are grouped into two age categories of about 30 participants each: 18-40 years, and 65 years of age and older, based upon their age at the time of initial enrollment.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately five years. You will receive the flu vaccine every year for 5 years. Each of these vaccine visits are followed by three follow-up visits (a total of 4 clinic visits for each flu vaccination). In addition, we will ask you to return to our clinic twice during the study, (at six and eighteen months after your first flu vaccine), to receive the Hepatitis A vaccine, by injection. The Hepatitis A vaccination also requires three follow-up clinic visits after the injection. All follow-up clinic visits occur at approximately 7, 14 and 28 days after each vaccination.

By signing this informed consent, you agree to participate in this year's study and participate in subsequent years until the end of the study-funding period. We also ask that you consider naming a proxy contact who could provide follow-up health information for you if you are unable to do so.

PROCEDURES

Flu Vaccination Portion:

If you choose to participate, Dr. Grant and her research study staff will ask you to attend 4 clinic visits each fall for the duration of the study (5 years), for the flu vaccine portion of the study. There is a study calendar, for your reference, located after the study visit descriptions on the following pages.

At Flu Vaccine Administration Study Visits 1, 9, 17, 25 and 30 (Day 0)

- These visits will last about 1 ½ hours.
- You will be given a complete description of the study. After you have reviewed and signed the informed consent, a screening procedure will be done to evaluate your eligibility to participate in the study. Information will be collected regarding your health and any medications that you may be taking.
- Vital signs, including temperature, pulse, respiratory rate, blood pressure, height and weight will be obtained during this visit. A brief clinical assessment will be completed, if indicated.
- If you have a fever, or are sick, you cannot be enrolled at this visit but may be asked to return later once your illness is resolved.
- Approximately 4 ½ tablespoons of blood will be collected from your arm to assess your baseline immune function status.
- You will be asked to bring a stool specimen twice during the study, in container provided to you in the mail - at the beginning of Year 1 and Year 4.
- You will receive a single dose of the seasonal flu vaccine by injection into the upper arm muscle.
    - In the 65 years and older group, you will be randomized to receive either Fluzone High-dose IIV4 or Fluad IIV4.
    - The randomization will be determined randomly, with a 50/50 chance of receiving either vaccine (like flipping a coin)
- You will be observed in the clinic for at least 15 minutes following vaccination to record any immediate reactions to the vaccine
- You will be provided with a memory aid diary, and instructed to record any changes in your health or medications. Proxy Contact materials will be discussed.
- During the visit, if you are age 65 or older, we will ask you to complete the Timed Up and Go test (if you are able) and a brief survey of common age-related changes in health. The Timed Up and Go test requires that you stand up from a standard chair and walk a distance of approximately 10 feet (measured as 3 meters), turn around and walk back to the chair and sit down again.

At Flu Vaccine Administration Study Visits 2, 10, 18, 26 and 31 (Day 7 ± 1 day following immunization)

- These visits will last about 25-30 minutes.
- We will review your memory aid diary for any changes in your health or medications.
- If indicated, your vital signs will be taken.

- If the functional assessments were not completed at the first visit, they will be completed at this visit.
- Approximately 4 ½ tablespoons of blood will be collected from your arm to assess your immune response to the vaccine.

At Flu Vaccine Administration Study Visits 3, 11, 19, 27 and 32 (Day 14, ± 2 days following immunization)

- These visits will last about 25-30 minutes.
- We will review your memory aid diary for any changes in your health or medications.
- If indicated, your vital signs will be taken.
- Approximately 4 ½ tablespoons of blood will be collected from your arm to assess your immune response to the vaccine.

At Flu Vaccine Administration Study Visits 4, 12, 20, 28 and 33 (Day 28, ± 3 days following immunization)

- These visits will last about 25-30 minutes.
- We will review your memory aid diary for any changes in your health or medications.
- If indicated, your vital signs will be taken.
- Approximately 4 ½ tablespoons of blood will be collected from your arm to assess your immune response to the vaccine.

Travel Vaccination Portion:
In the travel vaccine portion of the study, Dr. Grant and her research study staff will ask you to attend another 4 clinic visits for the Hepatitis A vaccine portion of the study.

For the Hepatitis A vaccination, you will return at six months and 18 months following your initial flu vaccination.

At Hepatitis A Vaccine Administration Study Visits 5 (Month 6 ± 14 days) and 13 (Month 18 ± 14 days)

- These visits will last about 1 ½ hours.
- We will review the signed informed consent and proceed after all your questions have been answered.
- Vital signs, including temperature, pulse, respiratory rate, blood pressure, height and weight will be obtained during this visit. A brief clinical assessment will be completed, if indicated.

- If you have a fever, or are sick, you cannot be enrolled at this visit but may be asked to return later once your illness is resolved.
- Approximately 4 ½ tablespoons of blood will be collected from your arm to assess your baseline immune function status.
- You will receive a single dose of the Hepatitis A vaccine by injection into the upper arm muscle. You will be observed in the clinic for at least 15 minutes following vaccination to record any immediate reactions to the vaccine.
- You will be provided with a memory aid diary, and instructed to record any changes in your health or medications. Proxy Contact materials will be reviewed.

At Hepatitis A Vaccine Follow-up Study Visits 6 and 14 (Day 7 ± 1 day)

- These visits will last about 25-30 minutes.
- We will review your memory aid diary for any changes in your health or medications.
- If indicated, your vital signs will be taken.
- Approximately 4 ½ tablespoons of blood will be collected from your arm to assess your immune response to the vaccine

At Hepatitis A Vaccine Follow-up Study Visits 7 and 15 (Day 14 ± 2 days)

- These visits will last about 25-30 minutes.
- We will review your memory aid diary for any changes in your health or medications.
- If indicated, your vital signs will be taken.
- Approximately 4 ½ tablespoons of blood will be collected from your arm to assess your immune response to the vaccine

At Hepatitis A Vaccine Follow-up Study Visits 8 and 16 (Day 28 ± 3 days)

- These visits will last about 25-30 minutes.
- We will review your memory aid diary for any changes in your health or medications.
- If indicated, your vital signs will be taken.
- Approximately 4 ½ tablespoons of blood will be collected from your arm to assess your immune response to the vaccine

At COVID-19 Assessment Study Visit

- This visit will last about 1 hour.

- We will review your memory aid diary for any changes in your health or medications.
- We will review the signed informed consent and proceed after all your questions have been answered.
- If indicated, your vital signs will be taken.
- Approximately 6½ tablespoons of blood will be collected from your arm to assess your immune response
- We will administer a survey to collect information regarding past COVID-19 infections and vaccinations.

Years 1-3 Study Calendar

Procedures	Enrollment/Baseline Visit 1, Day 0	Study Visit 2 Day 7 +/-1 day	Study Visit 3 Day 14 +/- 2 day	Study Visit 4 Day 28+/-3 day	Study Visit 5 Month 6+/-2 weeks	Study Visit 6 Day 7+/-1 day post-V5	Study Visit 7 Day 14+/-2day post-V5	Study Visit 8 Day 28 +/-3day post-V5	Study Visit 9 Month 12+/-2 weeks	Study Visit 10 Day 7+/-1 day post-V9	Study Visit 11 Day 14+/-2day post-V9	Study Visit 12 Day 28 +/-3day post-V9	Study Visit 13 Month 18+/-2 weeks	Study Visit 14 Day 7+/-1 day post-V13	Study Visit 15 Day 14+/-2day post-V13	Study Visit 16 Day 28 +/-3day post-V13	Study Visit 17 Month 24+/- 2 weeks	Study Visit 18 Day 7+/-1 day post-V17	Study Visit 19 Day 14+/-2 day post-V17	Study Visit 20 Day 28+/-3 day post-V17
Informed consent	X																			
Demographics	X																			
Medical history	X																			
Concomitant medication review	X	X----------																		X
Adverse event review and evaluation	X	X----------																		X
Vital signs	X				X				X				X				X			
Height	X								X								X			
Weight	X								X								X			
Frailty Index for Elderly	X								X								X			
CBC with differential	X				X				X				X				X			
Stool sample for microbiome	X																			
Other assessments (e.g., immunology assays)	X	X----------																		X
Randomize Elderly for influenza study vaccine	X																			
Administer influenza study vaccine	X								X								X			
Administer Hepatitis A study vaccine (optional)					X								X							
Complete Case Report Forms (CRFs)	X	X----------																		X

Years 3-5 Study Calendar

Procedures	Study Visit 25 Month 36+/-2 weeks	Study Visit 26 Day 7 +/- 1 day post-V25	Study Visit 27 Day 14+/- 2 day post-V25	Study Visit 28 Day 28+/- 3 day post-V25	Final Study Visit 29								
Informed consent					X								
Demographics													
Medical history					X								
Concomitant medication review	X----------X												
Adverse event review and evaluation	X----------X												
Vital signs	X				X								
Height	X				X								
Weight	X												
Frailty Index for Elderly	X												
CBC with differential	X												
Stool sample for microbiome	X												
Other assessments (e.g., immunology assays)	X----------X												
Administer Influenza study vaccine	X												
Administer Hepatitis A study vaccine (optional)													
COVID-19 Questionnaire					X								

Women of Childbearing Potential

You agree to notify the investigator as soon as possible if you become pregnant, which may result in your being withdrawn from the study.

Tissue Sampling for Future Immune-Related Research

Research using tissues is an important way to try to understand human disease. You have been given this information because the investigators want to include your blood samples in a research project and because they want to save the samples for future research. There are several things you should know before allowing your tissues to be studied.

Your blood/stool samples will be stored using a unique study identification number. The results of the study of your samples will be used for research purposes only and you will not be told the results of the tests.

Your samples will be analyzed and stored at Stanford University and by other researchers at Stanford and outside of Stanford, including sites participating in the NIH Human Immunology Project Consortium (HIPC). Your samples will be identified by your unique study ID code and study visit number. Your name will not be associated with any samples used for future research, but they may be identified by your age. By signing this consent form and agreeing to participate in the study, you agree to the use of your samples for future research.

Tissue Sampling for Immune-Related Genetic Testing

As part of the analysis on your samples, the investigators will do immune-related genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information such as personal appearance, and biochemistry, gene sequences, genetic landmarks, individual and family health history, and reactions to medications and responses to vaccination or treatment.
Genetic testing will be performed on coded specimens. Your name will not be associated with any samples used for future research, but they may be identified by your age.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

The results from the study of your research samples will be used for research purposes only and you will not be told the results of the tests. Your samples will be analyzed and stored at Stanford University. The goal of this research is to discover genetic factors that contribute to the prevention or treatment of illnesses.

Genetic information from analyses of your coded samples and a portion of your coded medical information may be stored in one of the National Institutes of Health (NIH) databases such as the NIH HIPC data repository (ImmPORT) and the National Center for Biotechnology Information databases (NCBI). These research results along with information from other research participants will be used for future research. These databases will be accessible by the Internet. Only anonymous information from the analyses will eventually be put in a completely public research database, available to anyone on the Internet.

No traditionally-used identifying information about you, such as your name, address, telephone number, or social security number, will be put into the public database. While the public database will not contain information that is traditionally used to identify you, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a blood relative) in another database and be able to identify you (or your blood relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you.

However, your privacy is very important to us and we will use safety measures to protect it. Despite all of the safety measures that we will use, we cannot guarantee that your identity will never become known.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant.
- Keep your memory aid updated as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

While participating in this research study, you should not take part in any other research project without the approval of the Protocol Directors of each study. This is to protect you from possible injury arising from such things as extra blood drawing, or other similar hazards.

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WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. You will not lose any benefits to which you would otherwise be entitled.

If you decide to stop your participation in this study, you should notify Dr. Philip Grant at (650) 723-9443. The following information will be collected if possible:

- We will ask about your current health status, medications, and note any changes since the previous visit.
- You will be encouraged to allow follow-up of any safety-related health events and to donate scheduled blood samples, if possible.

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

The discomforts associated with this study are those of having blood drawn from an arm vein and injection of the vaccine into the arm muscle. The vaccines used in this study are licensed by the FDA and are not experimental.

Drawing blood causes transient discomfort and may cause fainting. Bruising at the site of blood drawing may occur, but can be prevented or lessened by applying pressure immediately after the blood draw.

Intramuscular Flu injection may cause injection site pain, swelling, redness, muscle aches, and bruising. Immediate allergic reactions to vaccine, including anaphylaxis, are in general extremely rare (approximately 1 person in 4,000,000), and might occur as a skin rash such as hives, difficulty breathing, fainting, drop in the blood pressure and death. Such reactions can usually be stopped by emergency medications administered by study personnel.

Hepatitis A Vaccine recipients may develop systemic reactions such as fever, headaches, body aches, mild fussiness or crying, nausea, vomiting, stomach pain, diarrhea, loss of appetite, joint pain, sore throat, and fatigue.

These reactions are usually greatest within the first 24 to 72 hours after vaccination and last 1 to 2 days. Analgesics (*e.g.*, Ibuprofen or Tylenol®) and rest will generally relieve or moderate these symptoms. Other hypersensitivity reactions, including reactions resulting in large local swelling reactions, are also possible.

Guillain-Barré syndrome (GBS) is an extremely rare illness that can cause muscle weakness and paralysis that may last from a few days to months. Most people who develop GBS recover completely, but some people can be paralyzed for a prolonged time or even die. Although Guillain-Barré syndrome may have been associated with the 1976-1977 inactivated swine influenza vaccine and inactivated flu vaccines used in early 1990's, subsequent inactivated vaccines have not been associated with an increased risk of this condition. However, if there were a risk of GBS from current flu vaccines, it would be no more than 1 or 2 cases per million people vaccinated. This is much lower than the risk of severe influenza, which can be prevented by vaccination.

Participation in this study may involve risks to the participant, which are currently unforeseeable.

POTENTIAL BENEFITS

- There are no benefits for participating in this study other than receiving the protocol vaccines, which are available publicly.
- Participants given the influenza vaccines are likely to experience decreased frequency and severity of subsequent influenza infection. The beneficial role of influenza vaccination in the elderly adults has been recognized increasingly over the past several years as more information has become available about the high rate of illness and even death from this respiratory illness.
- Participation will help investigators understand the immune responses of persons to the influenza vaccine.
- We cannot and do not guarantee or promise that you will receive any benefits from this study.

ALTERNATIVES

The alternative to participating in this study is to receive the vaccines from another source. The vaccines are available publicly.

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PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director. You have the right to refuse to answer particular questions.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

ClinicalTrials.gov

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information (except for age) will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified.

The purpose of this research study is to obtain information on the immune response to various types of vaccines and to compare immune function between older and younger adults. The results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.
The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by NHI which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing

information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.
The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document, such as research data collected

Authorization to Use Your Health Information for Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

This is a research study of the immune response to the influenza vaccine (influenza is commonly known as "the flu") and other vaccines. Your health information may help to discover new biological markers that are associated with the age-related immune response to the seasonal flu vaccine in older adults compared with younger adults. Participants will be followed annually until the end of the funding period, in order to establish a valuable long-term study of immune responsiveness. Identifying differences in immune function between older and younger participants and among individual participants over time might help predict who will have a poor immune response to immunization.

The results will be provided to regulatory agencies as required. The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity (except for age) will not be disclosed.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study, including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information

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will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to:

Dr. Philip Grant
Department: Medicine - Med/Infectious Diseases
Stanford University School of Medicine
300 Pasteur Drive, Room S-101
Stanford, CA 94305-5107

What Personal Information Will Be Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to selected contact information and information required for clinic registration (name, telephone number, address, email, date of birth, race and ethnicity, medical record number), appointment reminders (email address, name, appointment dates), information required to process study reimbursements (social security number), your age, health information and results from blood tests used for immune-related research. Results from research tests will be labeled with your study ID and visit number, and your identity (except for age) will not be disclosed. Future use of your samples for research, including genetic testing, will be performed on coded specimens. The NIH Human Immunology Project Consortium (HIPC) data repositories (ImmPORT) will store the results of the research test results. Genetic data that is developed in this study will be made available to other researchers through the National Center for Biotechnology Information (NCBI) databases.

In the event that you have a change in your health status while taking part in the study and are hospitalized or seen at Stanford University Hospital, the research staff may access those medical records to evaluate the adverse event.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Other physicians, researchers, nurses, study coordinators and clinical research assistants who are members of the research team

- The Stanford Clinical and Translational Research Unit staff
- The Stanford Hospital Clinical Laboratories staff.

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The National Institutes of Health (NIH)
- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The Food and Drug Administration (FDA)

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will expire on December 31, 2064.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____
Print Name of LAR

_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

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Financial Considerations

Payment
You will receive $30.00 for each regularly scheduled clinic visit you complete in the form of a gift card or check payment. We will also provide parking vouchers for each of your visits. If you are unable to arrange transportation to your clinic appointments, transportation will be provided.

Payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive a check payment.

Costs
There is no cost to you for participating in this study, other than basic expenses like transportation and the personal time it will take to come to all of the study visits. Free parking is available at the research clinic at 800 Welch Road in Palo Alto.

Sponsor
The National Institutes of Health is providing financial support and/or material for this study. The National Institutes of Health are providing some financial support for the facility and staff where part or all of the study is taking place.

COVID-19 Related Requirements

If you are coming in-person to research visits, you are required to be fully vaccinated—2 doses (1 for Johnson and Johnson), 2 weeks out and to provide proof of your vaccination (e.g., CDC COVID-19 Vaccination Card, e-Health record, etc.) to the researcher prior to study participation. Alternately, you can provide a negative COVID test within 72 hours of your visit.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. You will be responsible for any associated co-payments or deductibles as required by your insurance.

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital. You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, **Philip Grant, M.D., at (650) 723-9443**. You should also contact him at any time if you feel you have been hurt by being a part of this study.

Appointment Contact: If you need to change your appointment, please contact the Stanford-LPCH Vaccine Program research staff at (650) 724-5551**.**
Alternate Contact: If you cannot reach the Protocol Director, please call the research coordinator at (650) 724-5551 **.**

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future Stanford-LPCH Vaccine Program studies that may be of interest to you?

____ Yes ____ No

Signing your name means you agree to be in this study and that you were given a copy of this consent form.

_____ _____

Signature of Adult Participant Date

_____

Print Name of Adult Participant

_____ _____

Signature of LAR (Parent, Guardian or Conservator) Date

_____

Print Name of Legally Authorized Representative

_____ _____

Signature of Person Obtaining Consent Date

_____

Print Name of Person Obtaining Consent