

Eligibility Criteria and Visit Schedule (SLVP website link)

Stanford U19 HIPC. Vaccination and infection: Indicators of immunological health and responsiveness
Project 1: Plasmablast trafficking and antibody response in influenza vaccination Year 4, Protocol
Amendment

This segment of the Vaccine Program website is designed to provide more detailed information to volunteers who are interested in participating in the study. There are three sections.

In the first section you will find a list of requirements you will need to meet in order to be considered for participation.

In the next section you will find events or conditions that might make you ineligible to participate.

In the last section you will find a table of study visits and procedures. This will give you a better idea of the study requirements and the time commitment involved.

Eligibility Requirements:

Section I. To be considered, you should meet these requirements:

1. Otherwise healthy, ambulatory between the ages of 8-34 years, inclusively.
2. Willing to complete the informed consent process including child assent if indicated.
3. Availability for follow-up for the planned duration of the study, at least 28 days after immunization.
4. We will review your/your child's health history and record blood pressure, pulse, respiratory rate, and oral temperature at the first study visit. It is possible we may not be able to enroll you at this visit based upon the information we collect.
5. Except for the new volunteers, a previous participant of study SLVP021

Section II. To be considered, you should ***not*** have any of these events or conditions that could put your health at risk if you were to participate in the study.

1. Have you gotten a flu immunization already for this year (2014-2015)?
2. Have you received a flu immunization in last 3 years, 2011, 2012 and 2013(**ONLY** for new participants)?
3. Do you have an allergy to egg or egg products, or to vaccine components, or thimerosal (TIV multi-dose vials only)
4. Have you ever had a life-threatening reaction to a vaccination?
5. Do you have any problems with your immune system or a history of immunodeficiency disorders (including HIV infection)?
6. Do you have any illness or conditions that may affect your immune system, such as liver disease, diabetes mellitus treated with insulin, moderate to severe kidney disease or any other chronic condition? If you do, I will need to discuss any conditions you may have with the study doctor before we schedule your visit(s).
7. Do you have a history of high blood pressure? If yes, is it well-controlled now? If your blood pressure is higher than >150 systolic or > 95 diastolic at your first visit, we may not be able to enroll you in the study.
8. Do you have a chronic Hepatitis B or Hepatitis C infection?
9. Have you recently, are you currently, or are planning to use a medication that could decrease your immune response during the study? This includes oral (systemic) steroids.
10. Have you, or do you now have any type of cancer (other than squamous cell or basal cell skin cancer), or a recurrence of cancer in the past year? This would include solid tumors, such as breast cancer, and any

cancers of the blood such as leukemia or lymphoma? If you do, I will need to discuss any condition you have with the study doctor before we can schedule your visits

11. Do you have an autoimmune disease (such as rheumatoid arthritis treated with medications such as Plaquenil, methotrexate, prednisone, Enbrel). If you do, I will need to discuss any conditions you may have with the study doctor before we schedule your visits.
12. Do you have a history of blood diseases or kidney diseases that required hospitalization or regular medical follow-up or hospitalization during the preceding year?
13. Do you take any anti-coagulation medications such as Coumadin or Lovenox, or anti-platelet agents such as aspirin (except aspirin up to 325 mg per day), Plavix, Aggrenox? If you do, we will need to discuss any conditions you may have with the study doctor before we schedule your visits.
14. Have you received a blood transfusion or any blood products such as platelets within the past 6 months? Are you planning to receive a blood transfusion or blood products during the study?
15. Have you donated blood within the past 6 weeks? If yes, when? Are you planning to donate blood during the one month study period?
16. Have you received any vaccinations within the past 2 months? If yes, which ones? (Inactivated vaccine should not be administered within 14 days prior to enrollment and live, attenuated vaccine within 60 days prior to enrollment)? Are you planning to receive any vaccinations during the one month study period?
17. Do you need an allergy shot (that cannot be postponed) during the one month study period?
18. Have you ever had a condition called Guillain-Barré Syndrome?
19. Are you currently pregnant or nursing?
20. Have you taken any experimental drugs or vaccines within past month or participated in any research studies? Are you planning to participate in another study during the study period?
21. Do you have any other conditions that would be important for us to know about? We are asking to make sure it is safe for you to participate in the study.
22. Is your work or personal schedule flexible enough to allow you to come to all of the study visits?
23. It is important for you to know that if you are feeling ill or have a fever on the day of your first visit, we will not be able to complete your visit and may have to reschedule. Please call before your appointment if you are not feeling well.

<u>Scheduling Appointments:</u>
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Section III. Study Visits/ Schedule

For all volunteers there will be 3 clinic visits at an outpatient clinic at Stanford - located in the Freidenrich Center for Translational Research (FCTR) at 800 Welch Road, Palo, CA 94304.

. At Visit 1, we will review informed consent and your eligibility. The first clinic visit will require approximately 1 hour completing. The remaining 2 visits will take approximately 20-25 minutes each. The second clinic visit will be 6-8 days after the vaccination. The third clinic visit will be 24-32 days after the vaccination. There will be a blood draw at each of the 3 study visits.

The visit schedule is as follows:

Appointment Schedule:

VISIT (Sept-Dec.)	VISIT TYPE	DATE	TIME
Visit 1, Day 0 1 hour	Visit 1, Consent/ Blood draw/Vaccination		
Visit 2, Day 6-8 20-30 minutes	Visit 2, Clinic Visit/Blood draw		
Visit 3, (28+4 days after Visit 1) 20-30 minutes	Visit 3, Clinic Visit/Blood draw		

Thank you for your interest in our research. **Please contact the study staff at (650) 498-7284** or email us at **vaccines_program@stanford.edu** if you have any questions.

We look forward to talking with you.