

Eligibility Criteria and Visit Schedule (SLVP website link)

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. Are you a healthy adult, 40-49 years of age (for Cross-Sectional study) or 50 years of age and older (for Vaccination study)?
2. Do you have a history of having had chicken pox in the past or have you lived within the continental U.S. for past 30 years?
3. At your first visit, we will review the informed consent that includes more information about study participation. You will need to read and sign the consent before we can enroll you in the study. Are you willing to review the informed consent? You can ask questions about the study any time - now and during your study visit(s).
4. Will you be available to complete the study visit(s) for the planned duration of the study? (Cross-sectional study includes 1 study visit; Vaccination study includes 5 study visits over a one month period).
5. We will review your health history and record your blood pressure, pulse, respiratory rate, and oral temperature at the first study visit. If any of these are abnormal, we may not be able to enroll you.

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 had shingles within the past 5 years?
2. Have you ever been given a vaccine for prevention of shingles (Zostavax vaccine)?
3. (Vaccination study only) Do you have a history of a *severe* allergic reaction to a vaccination or to vaccine components, including gelatin and neomycin?
4. (Vaccination study only) Have you ever had a life-threatening reaction to a vaccination?
5. (Vaccination study only) Do you weigh less than 110 lbs? If yes, you may not be able to participate in this study.
6. Do you have any problems with your immune system or a history of immunodeficiency disorders?
7. Do you have a chronic HIV, Hepatitis B or Hepatitis C infection?

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- 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).
- 8.
- 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 (corticosteroid nasal sprays, inhaled steroids and topical steroids for conditions such as asthma and allergies are permissible) .
- 9.
- 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.
- 10.
- Have you, or do you now have any type of cancer (other than squamous cell or basal cell skin cancer), and received chemotherapy treatment 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, we will need to discuss any condition with the study doctor. For males. You may be able to participate if you have prostate cancer as long as it hasn't spread and you are not undergoing treatment with medications.
- 11.
- 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?
- 12.
- Do you have an autoimmune disease such as rheumatoid arthritis treated with medications such as Plaquenil, methotrexate, prednisone, Enbrel (thyroid disease may be acceptable). If you do, I will need to discuss any conditions you may have with the study doctor before we schedule your visit(s).
- 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 daily), Plavix, Aggrenox? If you do, I will need to discuss any conditions you may have with the study doctor before we schedule your visit(s).
- 14.
- Have you taken any antiviral medications recently? You should not have taken any antiviral medications within 24 hrs. before your first study visits (and for the Vaccination Study: no antiviral medications should be taken for the 14 days following study vaccination).
- 15.
- Have you received any vaccinations within the past 2 months? Are you planning to get any immunizations within a month of study enrollment? (Inactivated vaccine should not be administered within 14 days prior to enrollment and live, attenuated vaccine within 60 days prior to enrollment. NOTE: for Vaccination Study: immunizations, other than with study vaccine, should be avoided during the study period-for 4-5 weeks).
- 16.
- Have you taken any experimental drugs or vaccines within past month or participated in any research studies? Vaccination Study: Are you planning to participate in another study during the study period?
- 17.
- Have you received a blood transfusion or any blood products such as platelets within the past 6 months?
- 18.
- Have you donated blood within the past 6 weeks? (If yes, when? Are you planning to donate blood during the time of your participation in this study?)
- 19.

20. Are you currently pregnant or nursing? Are you planning to become pregnant (pregnancy should be avoided for 3 months following administration of Zostavax vaccine)?

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. Will your work or personal schedule interfere with your ability to complete 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. We ask that you call before your appointment if you are not feeling well. Will this be a problem?

Scheduling Appointments:

Section III. Study Visits/ Schedule

For volunteers 40-49 years of age, there will be 1 clinic visits at Stanford. The visit will take about 1 hour.

For volunteers 50 years of age and older, there will be 5 clinic visits at Stanford over a one month period. Volunteers will also receive a free shingles vaccination.

The first clinic visit will require approximately 1- 1 1/2 hours to complete. The remaining 4 visits will take about 25 minutes each. The visit schedule is as follows:

Initial Study Visit (Cross-Sectional and Vaccination Studies)		Target Date	DATE	TIME
Visit 1, Day 0	Consent/ Hx/Blood draw Vaccination (Vaccination study only)			
VACCINATION STUDY (Continue with V02-V05)				
Visit 2 Day 1(+2)	Clinic Visit/Blood draw			
Visit 3, Day 7 - 9	Clinic Visit/Blood draw			
Visit 4 Day 14 (±2)	Clinic Visit/Blood draw			
Visit 5 Day 28 (±7)	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.

T Cell Responses to Varicella Zoster Virus After Vaccination and Viral Escape
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We look forward to talking with you.