

**Eligibility Criteria and Visit Schedule (SLVP website link)**  
Immune Senescence in the Elderly: Comparison of Immune Responses to  
Influenza Vaccine in Adults of Different Ages

This segment of the Vaccine Program website is designed to provide more detailed information to volunteers who are interested in participating in the influenza vaccine 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:**

I. To be considered, you must meet these requirements:

1. Between the ages of 18-30, or 60-100 years, inclusive at time of initial enrollment.
2. Good general health as determined by a screening medical history and brief physical examination.
3. No acute illness at time of vaccination.
4. Willing and able to sign Informed Consent
5. Available for follow-up for the planned duration of the study

II. To be considered, you must ***not*** have any of these events or conditions that could put your health at risk if you were to participate in the study. The study doctors and nurses will also discuss this information in more detail during your screening visit.

1. Prior vaccination with TIV or LAIV in Fall 2009
2. Adult ages <18, 31-59 or >100 years at time of initial enrollment
3. Allergy to egg or egg products
4. Allergy to vaccine components, including thimerosal
5. Active systemic or serious concurrent illness, including febrile illness on the day of vaccination
6. History of immunodeficiency
7. Known or suspected impairment of immunologic function, including, but not limited to, clinically significant liver disease, diabetes mellitus treated with insulin, moderate to severe renal disease, blood pressure >150/95 at screening, or any other chronic disorder which, in the opinion of the investigator, might jeopardize volunteer safety or compliance with the protocol.

8. Hospitalization in the past year for congestive heart failure or emphysema.
9. Chronic Hepatitis B or C.
10. Recent or current use of immunosuppressive medication, including glucocorticoids (corticosteroid nasal sprays are permissible).
11. Malignancy, other than squamous cell or basal cell skin cancer (includes solid tumors such as breast cancer or prostate cancer with recurrence in the past year, and any hematologic cancer such as leukemia).
12. Autoimmune disease (including rheumatoid arthritis treated with immunosuppressive medication such as Plaquenil, methotrexate, prednisone, Enbrel) which, in the opinion of the investigator, might jeopardize volunteer safety or compliance with the protocol.
13. History of blood dyscrasias, renal disease, or hemoglobinopathies requiring regular medical follow up or hospitalization during the preceding year
14. Use of any anti-coagulation medication such as Coumadin or Lovenox, or anti-platelet agents such as aspirin, Plavix, Aggrenox. May be acceptable after review by investigator.
15. Receipt of blood or blood products within the past 6 months
16. Medical or psychiatric condition or occupational responsibilities that preclude subject compliance with the protocol
17. Inactivated vaccine 14 days prior to vaccination
18. Live, attenuated vaccine within 60 days of vaccination
19. History of Guillain–Barré Syndrome
20. Pregnant or lactating woman
21. Use of investigational agents within 30 days prior to enrollment
22. Donation of the equivalent of a unit of blood within 6 weeks prior to enrollment
23. Any condition which, in the opinion of the investigator, might interfere with volunteer safety, study objectives or the ability of the participant to understand or comply with the study protocol.

### **Scheduling Appointments:**

### **III. Study Visits/ Schedule**

There will be 3 clinic visits and 1 follow-up phone call about 6-8 months after your first study visit..

You will receive the seasonal influenza vaccination at the first clinic visit. The second clinic appointment will be approximately 5-7 days after the vaccination. The third clinic visit will be between 21-35 days after the vaccination. There will be a blood draw at each of the three clinic visits.

The first clinic visit will require approximately 1 hour to complete. The remaining 2 visits will take approximately 25 minutes each. The phone call will require no more than 15 minutes.

The visit schedule is as follows:

<b>Window</b>	<b>Visit</b>	<b>Date</b>	<b>Time</b>
<b>Year - 2009-10:</b> Visit 1, Day 0	Visit 1: Consent/ Vaccination/ Blood draw		
Visit 2 Day 5 (+2)	Visit 2: Clinic Visit/ Blood draw		
Visit 3 Day 28 ( $\pm 7$ )	Visit 3: Clinic Visit/ Blood draw		
Phone Call ( 6 months after Visit 1)	Phone Call		

Thank you for your interest in our research. **Please contact the study staff at (650) 498-7284** if you have any questions. We look forward to talking with you.