

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 and 30, or 60-100 years, inclusive.
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. Adult ages <18, 31-59 or >100 years
2. Allergy to egg or egg products
3. History of immunodeficiency
4. Known or suspected impairment of immunologic function, including, but not limited to, clinically significant liver disease, diabetes mellitus, moderate to severe renal disease or any other chronic disorder
5. Active systemic or serious concurrent illness, including febrile illness on the day of vaccination
6. Use of immunosuppressive medication, including glucocorticoids (corticosteroid nasal sprays are permissible)
7. Malignancy, other than squamous cell or basal cell skin cancer
8. Autoimmune disease

9. History of blood disorders, renal disease, or blood disorders requiring regular medical follow up or hospitalization during the preceding year
10. Receipt of blood or blood products within the past 6 months
11. Medical or psychiatric condition or occupational responsibilities that preclude subject compliance with the protocol
12. Any chronic condition which, in the opinion of the investigator, might jeopardize volunteer safety or compliance with the protocol
13. Inactivated vaccine 14 days prior to vaccination
14. Live, attenuated vaccine within 60 days of vaccination
15. History of Guillain–Barré Syndrome
16. Pregnant or lactating woman
17. Allergy to vaccine components, including thimerosal
18. Use of investigational agents within 30 days prior to enrollment
19. Donation of the equivalent of a unit of blood within 6 weeks prior to enrollment
20. 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.

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

There will be 3 clinic visits and 1 follow-up phone call at six months during each year of the three years of the study. You will receive the seasonal influenza vaccination at the first clinic visit each year. The second clinic appointment will be approximately 5-7 days after the vaccination. The third clinic visit will be between 28-32 days after the vaccination. 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:

Window	Visit	Date	Time
Year 1: Visit 1, Day 0	Visit 1, Consent/ Vaccination		
Year 1: Visit 2 Day 5 (+2)	Visit 2 Clinic Visit		
Year 1: Visit 3 Day 28 (+4)	Visit 3/ Clinic Visit		
Year 1: Phone Call (6 months after Visit 1)	Phone Call		
Year 2: Visit 1, Day 0	Visit 1, Consent/ Vaccination		

Year 2: Visit 2 Day 5 (+2)	Visit 2 Clinic Visit		
Year 2: Visit 3 Day 28 (+4)	Visit 3/ Clinic Visit		
Year 2: Phone Call (6 months after Visit 1)	Phone Call		
Year 3: Visit 1, Day 0	Visit 1, Consent/ Vaccination		
Year 3: Visit 2 Day 5 (+2)	Visit 2 Clinic Visit		
Year 3: Visit 3 Day 28 (+4)	Visit 3/ Clinic Visit		
Year 3: 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.