

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 – Year 8

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) Prior participant in any of Years 1-7 of the study or a 18-30 year old new participant.
- 2) Good general health at time of initial enrollment
- 3) Willing and able to sign Informed Consent
- 4) Available for follow-up for the planned duration of the study
- 5) Acceptable medical history by screening evaluation and brief clinical assessment

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.

Exclusion Criteria for Initial Study Enrollment (Development of these conditions following enrollment must be discussed with the investigator but may not exclude continued participation in the study)

- 1) History of immunodeficiency
- 2) Any chronic disorder which might jeopardize volunteer safety or compliance with the protocol (may include illnesses or conditions which could affect the immune system, such as liver disease, diabetes mellitus treated with insulin, moderate to severe kidney disease or any other chronic condition). May be acceptable after review by the investigator.

- 3) Blood pressure >150 systolic or > 95 diastolic at Visit 1
- 4) Chronic Hepatitis B or C.
- 5) Recent or current use of immunosuppressive medication, including glucocorticoids (corticosteroid nasal sprays and inhaled steroids are permissible). Use of oral steroids (<20mg prednisone-equivalent/day) may be acceptable after review by the investigator.
- 6) 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) which, in the opinion of the investigator, might jeopardize volunteer safety or compliance with the protocol.
- 7) 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.
- 8) History of blood dyscrasias or hemoglobinopathies requiring regular medical follow up or hospitalization during the preceding year
- 9) Use of any anti-coagulation medication such as Coumadin or Lovenox or anti-platelet agents such as aspirin (except aspirin up to 325 mg daily), Plavix, Aggrenox must be reviewed by investigator to determine if this would affect the volunteer's safety
- 10) Medical or psychiatric condition or occupational responsibilities that preclude subject compliance with the protocol
- 11) History of Guillain–Barré Syndrome
- 12) Pregnant. A breastfeeding woman may be evaluated by the protocol director to determine if participation would affect the volunteer's safety and may be included at the discretion of the investigator. Blood sample collection will be adjusted as necessary for volunteers safety.
- 13) A current member of the clinical study team
- 14) 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.

Exclusion Criteria for Annual Vaccination

- 1) Prior off-study vaccination with the current season influenza vaccine (TIV or LAIV)
- 2) Allergy to egg or egg products
- 3) Allergy to vaccine components, including thimerosal
- 4) Active systemic or serious concurrent illness, including febrile illness on the day of vaccination
- 5) Receipt of blood or blood products within the past 6 months or planned receipt of blood products prior to completion of study visits.

- 6) Receipt of inactivated vaccine 14 days prior to study vaccination or planned vaccination prior to completion of Visit 03 (~Day 28 after study vaccination).
- 7) Receipt of live, attenuated vaccine within 60 days of study vaccination or planned vaccination prior to completion of Visit 03 (~Day 28 after study vaccination).
- 8) Donation of the equivalent of a unit of blood within 6 weeks prior to enrollment or planned blood donation prior to completion of Visit 03 (~Day 28 after study vaccination).
- 9) Use of investigational agents within 30 days prior to enrollment or planned use of investigational agents prior to completion of study visits.
- 10) Need for allergy immunizations (that cannot be postponed) during the study period, V01 to V03 (~Day 28).
- 11) Pregnant or lactating woman. A woman who is pregnant or breastfeeding may be evaluated by the protocol director to determine if participation would affect volunteer safety and may be included at the discretion of the investigator. Blood sample collection will be adjusted as necessary for volunteer safety (e.g. blood collection volume for a pregnant woman would follow the minimal risk guidelines of 50 ml in an 8 week period and collection may not occur more frequently than 2 times per week).
- 12) 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. You will receive the licensed seasonal influenza vaccination at the first clinic visit. The second clinic appointment will be approximately 6-8 days after the vaccination. The third clinic visit will be between 21-35 days after the vaccination and a phone call visit approximately 6 months after enrollment. There will be a blood draw at each of the clinic visits.

The first clinic visit will require approximately 1 – 1 ½ hours to complete. The remaining 2 visits will take approximately 25 minutes each. The phone contact at visit 4 will require about 15 minutes.

The visit schedule is as follows:

Window	Visit	Date	Time
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Year - 2013-2014: Visit 1, Day 0	Visit 1: Consent/ Vaccination/ Blood draw		
Visit 2 Day 7 (± 1)	Visit 2: Clinic Visit/ Blood draw		
Visit 3 Day 28 (± 7)	Visit 3: Clinic Visit/ Blood draw		
Visit 4 Spring 2015- End of flu season	Visit 4: Phone Contact		
** ANNUAL PHONE FOLLOW-UP ONLY	-----		

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.