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 5

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 Years 1, 2, 3 and/or 4 of this study or new enrollment in Year 5.
   2) Age 18-30, 60-79, or 80-100 years inclusive at time of initial study enrollment
   3) General good health and ambulatory at time of enrollment
   4) No acute illness at time of vaccination
   5) Willing and able to sign Informed Consent
   6) Available for follow-up for the planned duration of the study
   7) Acceptable medical history by screening evaluation and brief clinical assessment
   8) Female volunteers of childbearing potential must use an acceptable method of contraception and not become pregnant for the duration of the clinical phase of the study (approximately 1 month). (Acceptable contraception may include implants, injectables, combined oral contraceptives, effective intrauterine devices (IUDs), sexual abstinence, or a vasectomized partner).

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 off-study vaccination with the 2011-2012 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) History of immunodeficiency (including HIV infection)
6) Any chronic disorder which, in the opinion of the investigator, might jeopardize volunteer safety or compliance with the protocol.
7) Blood pressure >150 systolic or > 95 diastolic at Visit 1
8) Chronic Hepatitis B or C.
9) 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.
10) 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.
11) Autoimmune disease (including rheumatoid arthritis treated with immunosuppressive medication such as Plaquinil, methotrexate, prednisone, Enbrel) which, in the opinion of the investigator, might jeopardize volunteer safety or compliance with the protocol.
12) History of blood dyscrasias or hemoglobinopathies requiring regular medical follow up or hospitalization during the preceding year
13) 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
14) Receipt of blood or blood products within the past 6 months
15) Medical or psychiatric condition or occupational responsibilities that preclude subject compliance with the protocol
16) Receipt of inactivated vaccine 14 days prior to vaccination
17) Receipt of live, attenuated vaccine within 60 days of vaccination
18) History of Guillain–Barré Syndrome
19) Pregnant or lactating woman
20) Use of investigational agents within 30 days prior to enrollment
21) Donation of the equivalent of a unit of blood within 6 weeks prior to enrollment
22) 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 4 clinic visits. 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 and the last 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 3 visits will take approximately 25 minutes each.

The visit schedule is as follows:

<table>
<thead>
<tr>
<th>Window</th>
<th>Visit</th>
<th>Date</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year - 2011-2012:</td>
<td>Visit 1: Consent/ Vaccination/ Blood draw</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visit 1, Day 0</td>
<td>Visit 2: Clinic Visit/ Blood draw</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visit 2 Day 5 (+2)</td>
<td>Visit 3: Clinic Visit/ Blood draw</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visit 3 Day 28 (+7)</td>
<td>Visit 4: Clinic Visit/ Blood draw</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visit 4 Day 180 (+14)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.