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:

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

1. An adult between 18 – 30 years of age and a twin (identical or fraternal)  
   **OR** an adult between 40 – 64 years of age and a twin (identical or fraternal)  
   **OR** an adult between 65– 100 years of age and an identical twin.
2. In good general health with no acute illness at the time of enrollment into the study. Able to come for visits at the Stanford clinic
3. Willing to complete the informed consent process
4. Available for three to four clinic visits in a one month period between September and December 2011.
5. Eligible by your medical history and a brief screening evaluation and physical assessment on the day of enrollment.
6. All female participants 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 to completion of Visit 3). Acceptable contraception includes implants, injectables, combined oral contraceptives, effective intrauterine devices (IUDs), sexual abstinence, or a vasectomized partner.

Section 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.

1. Have you gotten a flu immunization already this year (2011-2012)?
2. Do you have an allergy to egg or egg products, or to vaccine components, including latex or thimerosal? Will discuss the latex allergy with our study doctor to make sure it is safe for you to participate.
3. Have you ever had a life-threatening reaction to a vaccination?
4. Do you have any problems with your immune system or a history of immunodeficiency disorders (including HIV)?
5. 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, Will need to discuss any conditions you may have with the study doctor before we schedule your visit(s).
6. 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.
7. Have you been hospitalized in the past year for congestive heart failure or emphysema?
8. Do you have a chronic Hepatitis B or Hepatitis C infection?
9. 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 inhaled steroids, nasal sprays and topical steroids for allergies are permissible. Use of oral steroids will be reviewed by the investigator].
10. Have you, or do you now have any type of cancer (other than squamous cell or basal cell skin cancer), 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, I will need to discuss any condition you have with the study doctor before we can schedule your visits.

11. Do you have an autoimmune disease (such as rheumatoid arthritis treated with medications such as Plaquenil, methotrexate, prednisone, Enbrel). If you do, will need to discuss any conditions you may have with the study doctor before we schedule your visits.

12. 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?

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 per day), Plavix, Aggrenox? If you do, will need to discuss any conditions you may have with the study doctor before we schedule your visits.

14. Have you received a blood transfusion or any blood products such as platelets within the past 6 months?

15. Have you donated blood within the past 6 weeks?

16. Have you received any vaccinations within the past 2 months? If yes, which ones?

17. Have you ever had a condition called Guillain–Barré Syndrome?

18. Are you currently pregnant or nursing?

19. Have you taken any experimental drugs or vaccines within past month or participated in any research studies? Are you planning to participate in another study during the study period?

20. 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.

21. Is your work or personal schedule flexible enough to allow you to come to all of the study visits?

22. 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. Please call before your appointment if you are not feeling well.

Scheduling Appointments:

Section III. Study Visits/ Schedule
There will be 3-4 clinic visits at Stanford within a one month-period between September - December. You may also be asked to participate in a sub-study.

**Group B - 18-30 years old, identical twins: 4 clinic visits**
You will complete 4 clinic visits. At the first visit, you will review the informed consent, your health history and eligibility, and receive a flu shot in the arm. The second clinic visit will be 1 day after your vaccination. The third clinic visit will be 7-10 days after the vaccination. The fourth clinic visit will be 24-32 days after the vaccination. There will be a blood draw at each of the 4 study visits.

**Groups C (18-30 yr. old fraternal twins), D and E (all 40-64 yr. old twins): 3 clinic visits**
You will complete 3 clinic visits. At Visit 1, you will review the informed consent, health history and eligibility, and receive a flu shot in the arm. The second clinic visit will be approximately 7-10 days after the vaccination. The third clinic visit will be 24-32 days after the vaccination. There will be a blood draw at each of the 3 study visits.

**Group F - 65-100 yr old identical twins (3 or 4 clinic visits)**
You and your twin sibling will have the option to participate in a special sub-study together. If you choose to participate in the sub-study, you will complete 4 clinic visits. At the first clinic visit, you will review the informed consent, your health history and eligibility, and be randomly assigned to receive a flu shot in the arm (either the standard flu shot or the High-Dose flu shot). The second clinic visit will be 1 day after your vaccination. The third clinic visit will be 7-10 days after the vaccination. The fourth clinic visit will be 24-32 days after the vaccination. There will be a blood draw at each of the 4 study visits.

If you choose not to participate in the sub-study, you will complete 3 study visits as described for Groups C, D and E above. There will be a blood draw at each of the 3 study visits.

The visit schedule for all Groups is as follows:
<table>
<thead>
<tr>
<th>Visit</th>
<th>Visit Type</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Visit 1, Day 0</strong></td>
<td>Clinic Visit</td>
</tr>
<tr>
<td>1-1 ½ hours</td>
<td>Consent/ Health History/ Blood draw/ Vaccination/Questionnaires</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Visit 1A, Day 1</strong> (for Sub-study only)</td>
<td>Sub-study Clinic Visit /Blood draw</td>
</tr>
<tr>
<td>20-30 minutes</td>
<td></td>
</tr>
<tr>
<td><strong>Visit 2, Day 7-10</strong></td>
<td>Clinic Visit</td>
</tr>
<tr>
<td>20 to 30 minutes</td>
<td>/Blood draw</td>
</tr>
<tr>
<td><strong>Visit 3, Day 24 - 32</strong></td>
<td>Clinic Visit</td>
</tr>
<tr>
<td>20 to 30 minutes</td>
<td>/Blood draw</td>
</tr>
</tbody>
</table>

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.**

We look forward to talking with you.

For general information about participant rights, contact 1-866-680-2906