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. Inclusion:** To be considered, you must meet these requirements:

1. Are you generally healthy, ages 18-30 years old?
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 August 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 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.

**II. Exclusion:** 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. Did you get a flu immunization last year (2010-2011)?
2. Have you gotten a flu immunization already this year (2011-2012)?
3. Do you have an allergy to egg or egg products, or to vaccine components, including gentamicin, gelatin, arginine or MSG (for LAIV only), or thimerosal (TIV multi-dose vials only)
4. Have you ever had a life-threatening reaction to a vaccination?

5. Have you ever had or do you currently have asthma or wheezing?

6. Do you have any problems with your immune system or a history of immunodeficiency disorders (including HIV infection)?

7. 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, I will need to discuss any conditions you may have with the study doctor before we schedule your visit(s).

8. 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.

9. Have you been hospitalized in the past year for congestive heart failure or emphysema?

10. Do you have a chronic Hepatitis B or Hepatitis C infection?

11. Have you recently, are you currently, or are planning to use a medication that could decrease your immune response during the study? If yes, I will need to discuss with the study doctor before we schedule your visit(s).

12. Are you in close contact with anyone who has a severely weakened immune system?

13. 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, we will need to discuss any condition you have with the study doctor before we can schedule your visits.

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

15. 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?

16. 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, we will need to discuss any conditions you may have with the study doctor before we schedule your visits.

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

18. Have you donated blood within the past 6 weeks? (ineligible if donated the equivalent of a unit of blood within 6 weeks prior to enrollment- may be able to delay enrollment in order to participate)

19. Have you received any vaccinations within the past 2 months? If yes, check with study staff.

20. Have you ever had a condition called Guillain–Barré Syndrome?
21. Are you currently pregnant or nursing?
22. 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?
23. 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.
24. Is your work or personal schedule flexible enough to allow you to come to all of the study visits?
25. 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 4 week period (between September – December 2011). You can choose to be in the sub-study if your schedule is flexible for an extra clinic visit.

18-30 years old, (3 clinic visits)
You will complete 3 clinic visits. At Visit 1, you will review the informed consent, your health history and eligibility, and be randomly assigned to receive a single dose of the flu vaccine either in the arm (intramuscular or intradermal injection) or the nasal flu vaccine. The second clinic visit will be 6-8 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.

Sub-study: 18-30 years old, (4 clinic visits)
You will complete 4 clinic visits. At Visit 1, you will review the informed consent, your health history and eligibility, and be randomly assigned to receive a single dose of the flu vaccine either in the arm (intramuscular or intradermal injection) or the nasal flu vaccine. The second clinic (1A) visit will be 5 days after the vaccination. The third clinic visit will be 7 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. The completion of the sub-study visits exactly on Day 5 and Day 7 is very important to the success of the trial. The last study visit allows some flexibility in scheduling.

The visit schedule is as follows:
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](mailto:vaccines_program@stanford.edu) if you have any questions.

We look forward to talking with you.

<table>
<thead>
<tr>
<th>Visit</th>
<th>Visit Type</th>
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<tbody>
<tr>
<td><strong>Visit 1, Day 0</strong>&lt;br&gt;1 ½ hours</td>
<td>Clinic Visit/Informed Consent/Health History/Blood draw/ Vaccination/ Questionnaires</td>
</tr>
<tr>
<td><strong>Visit 1A, Day 5 (Sub-study only)</strong>&lt;br&gt;20 to 30 minutes</td>
<td>Clinic Visit /Blood draw</td>
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<tr>
<td><strong>Visit 2, Day 6-8</strong>&lt;br&gt;(Sub-study Day 7 only)&lt;br&gt;20 to 30 minutes</td>
<td>Clinic Visit /Blood draw</td>
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<tr>
<td><strong>Visit 3, Day 24-32</strong>&lt;br&gt;20 to 30 minutes</td>
<td>Clinic Visit /Blood draw</td>
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