

Eligibility Criteria and Visit Schedule (SLVP website link)

Fall 2009 Protocol for T-cell Immunity, Single-cell Phospho-protein Signaling And Genomic Approaches to B-cell Repertoire After Influenza Immunization

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. A child between 8 – 17 years of age and an identical twin **OR**
an adult between 18 – 30 years of age and a twin **OR**
an adult between 40 – 49 years of age and a twin **OR**
an adult between 70 – 100 years of age (twins and non-twins)
- ____ 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 clinic visits in a one month period between September and December 2009.
- ____ 5. Eligible by your medical history and a brief screening evaluation and physical assessment on the day of enrollment.
- ____ 6. If female and able to get pregnant, willing to use an acceptable method of birth control and not become pregnant for the duration of your participation in the study.

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. Already received your seasonal flu vaccination in the Fall of 2009
- ____ 2. Allergy to egg or egg products, or to vaccine components
- ____ 3. Life-threatening reaction to previous flu vaccinations
- ____ 4. Asthma [for LAIV (nasal spray) groups only]
- ____ 5. Any illness or fever on the day of your vaccination
- ____ 6. History of a weakened immune system
- ____ 7. Possible impairment of your immune system
- ____ 8. Hospitalization in the past year for congestive heart failure or emphysema
- ____ 9. Chronic Hepatitis B or C
- ____ 10. Recent or current use of a medication(s) that could weaken your immune system,
- ____ 11. Close contact with anyone who has a severely weakened immune system (for LAIV groups only)
- ____ 12. Cancer, other than squamous cell or basal cell skin cancer
- ____ 13. Autoimmune disease, a disease in which the immune system attacks your body's
own tissues
- ____ 14. History of a blood disorder or kidney disease that requires regular medical follow up or has resulted in
hospitalization during the past year

- ___15. Use of a blood thinning medication to prevent blood clots, unless approved by investigator
- ___16. Receipt of a blood or platelet transfusion in the past 6 months
- ___17. Mental illness that may interfere with your compliance to the study procedures
- ___18. Receipt of an inactivated (killed) vaccine within two weeks of vaccination
- ___19. Receipt of a live, attenuated vaccine within two months of vaccination
- ___20. History of Guillain–Barré Syndrome
- ___21. Pregnant or breast feeding
- ___22. Use of an experimental study drug in the past month
- ___23. Donation of a unit of blood in the past 6 weeks

<u>Scheduling Appointments:</u>
--

Section III. Study Visits/ Schedule

There will be 3 clinic visits at Stanford within a one month-period (September - December).

You will receive the assigned influenza vaccine, either as a flu shot in the arm or by intranasal spray. The second clinic appointment will be approximately 9-14 days after the vaccination. The third clinic visit will be between 24-32 days after the vaccination. There will be a blood draw at each of the three clinic visits.

The first clinic visit will require approximately 1 to 1 ½ hours to complete. The remaining 2 visits will take approximately 25 minutes each. The visit schedule is as follows:

Window	Visit	Date	Time
<u>September – December 2009</u>			
Visit 1, Day 0 1 to 1 ½ hours	Visit 1: Consent/ Vaccination/Blood draw		
Visit 2, Day 9-14 20 to 30 minutes	Visit 2: Clinic Visit / Blood draw		
Visit 3, Day 28 (± 4) 20 to 30 minutes	Visit 3: Clinic Visit / Blood draw		

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.