

**Eligibility Criteria and Visit Schedule (SLVP website link)**

U19 CCHI: Adaptive and Innate Immunity, Memory and Repertoire in Vaccination and Infection  
Project 2: Innate and Acquired Immunity to Influenza Infection and Immunization Vaccination  
2014-2019

This segment of the Vaccine Program website is designed to provide more detailed information to volunteers who are interested in participating in the 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 should meet these requirements:

1. Otherwise healthy, 6 mo-49 years old volunteers
2. Willing to complete the informed consent process (including assent for minors older than 7 years old).
3. Availability for follow-up for the planned duration of the study.
4. For parents of children 6 months – 4 years of age: Willing to participate in the study annually for up to 5 years (if yes, consider for annual return groups).
5. Acceptable medical history by review of inclusion/exclusion criteria and vital signs.
6. Influenza vaccine-naïve or only one prior season of flu immunization with a flu injection (does not apply to volunteers age 9 and above).

**Section II.** To be considered, you should not have any of these events or conditions that could put your health at risk if you were to participate in the study.

1. Prior off-study vaccination with the current year's seasonal influenza vaccine
2. Receipt of nasal spray influenza vaccine in the prior season (does not apply to volunteers age 9 and above)
3. Received flu immunizations in 2 or more prior flu seasons (does not apply to volunteers age 9 and above)
4. Allergy to egg or egg products, or to vaccine components, including gentamicin, gelatin, arginine or MSG (nasal spray vaccine)
5. Life-threatening reactions to previous influenza vaccinations
6. Asthma or history of wheezing (only for volunteers receiving nasal spray vaccine)
7. Active systemic or serious concurrent illness, including febrile illness on the day of vaccination
8. History of immunodeficiency (including HIV infection)
9. In children, daily aspirin therapy for any chronic medical condition
10. Known or suspected impairment of immunologic function, including, but not limited to, clinically significant liver disease, diabetes mellitus treated with insulin, moderate to severe renal disease, or any other chronic disorder which, in the opinion of the investigator, might jeopardize volunteer safety or compliance with the protocol.
11. Blood pressure >150 systolic or >95 diastolic at first study visit and the day of vaccination (for children 12 yrs and older, and adults).
12. Hospitalization in the past year for congestive heart failure or emphysema.
13. Chronic Hepatitis B or C

14. Recent or current use of immunosuppressive medication, including systemic glucocorticoids (corticosteroid nasal sprays and topical steroids are permissible in all groups; inhaled steroid use is not permissible)
15. Participants in close contact with anyone who has a severely weakened immune system should not receive LAIV4
16. 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).
17. 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
18. History of blood dyscrasias, renal disease, or hemoglobinopathies requiring regular medical follow up or hospitalization during the preceding year
19. Use of any anti-coagulation medication such as Coumadin or Lovenox, or anti-platelet agents such as aspirin (except up to 325 mg. per day), Plavix, or Aggrenox must be reviewed by investigator to determine if this would affect the volunteer's safety.
20. Receipt of blood or blood products within the past 6 months or planned used during the study
21. Medical or psychiatric condition or occupational responsibilities that preclude participant compliance with the protocol
22. Receipt of Inactivated vaccine 14 days prior to study enrollment, or planned vaccinations prior to completion of last study visit
23. Receipt of live, attenuated vaccine within 60 days prior to enrollment of planned vaccination prior to completion of last study visit
24. Need for allergy immunization (that cannot be postponed) during the study period
25. History of Guillain-Barré syndrome
26. Pregnant woman
27. Use of investigational agents within 30 days prior to enrollment or planned use during the study
28. Donation of the equivalent of a unit of blood within 6 weeks prior to enrollment or planned donation prior to completion of the last visit
29. 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.

<b><u>Scheduling Appointments:</u></b>
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### Section III. Study Visits

For all volunteers there will be total of 2- 4 clinic visits depending upon the age group and vaccine assignment. At Visit 1, we will review informed consent and study eligibility. The first clinic visit will require approximately 1 hour completing. You or your child will receive a FDA licensed seasonal vaccine at this visit. This is the same vaccine that will be used for public during the fall flu season. The remaining visits will take approximately 20-30 minutes each. All the visits will be at an outpatient clinic at Stanford - located in the Freidenrich Center for Translational Research (FCTR) at 800 Welch Road, Palo, CA 94304. You or your child will be assigned to the following groups based on age groups:

**Children 6- 23 months old:** Your child will receive a quadrivalent inactivated influenza vaccine given by intramuscular injection (IM). Your child's participation in the study will last for approximately 1 to 5 weeks depending on if they've had a flu vaccine in a prior year. Your child will be asked to attend 2-3 clinic visits at an outpatient clinic of Stanford Hospital Small amount of blood will be collected at some of the visits.

**Children 2 -4 years old:** Your child will receive a quadrivalent attenuated influenza vaccine given as a nasal spray. Your child's participation in the study will last for approximately 1-4 weeks depending on if

they've had a flu vaccine in a prior year. Your child will be asked to attend 2-4 clinic visits at an outpatient clinic of Stanford Hospital. Small amount of blood OR nasal swab samples from child's nasal passages will be collected at some of the visits.

**Children 9-13 years old and adults 18-49 years old:** You or your child will receive either a quadrivalent attenuated influenza vaccine given as a nasal spray OR a quadrivalent inactivated influenza vaccine given by intramuscular injection (IM) and will be asked to attend 3-4 clinic visits. You or your child's participation in the study will last for approximately 4 weeks. Blood and/or nasal swab samples will be collected at some visits.

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