

Eligibility Criteria and Visit Schedule (SLVP website link)

U19 CCHI: Adaptive and Innate Immunity, Memory and Repertoire in Vaccination and Infection
Project 1: The Role of CD4+ Memory Phenotype, Memory, and Effector T-cells in Vaccination and Infection- Influenza-specific DR1501+ or DR0701+ T cells

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 18-49 years old identical (MZ) twins who have previously participated in flu vaccine study. Both twins in the pair must be willing to participate in the study.
2. Willing to complete the informed consent process
3. Availability for follow-up for the planned duration of the study at least 28 days after immunization.
4. Acceptable medical history by review of inclusion/exclusion criteria and vital signs.

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. Allergy to egg or egg products, or to vaccine components, including gentamicin, gelatin, arginine or MSG (Flumist)
3. Life-threatening reactions to previous influenza vaccinations
4. Asthma or history of wheezing for (contraindication for receiving Nasal Flu mist)
5. Active systemic or serious concurrent illness, including febrile illness on the day of vaccination
6. History of immunodeficiency (including HIV infection)
7. 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.
8. Blood pressure >150 systolic or >95 diastolic at first study visit and the day of vaccination.
9. Hospitalization in the past year for congestive heart failure or emphysema.
10. Chronic Hepatitis B or C.
11. 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)

12. Participants in close contact with anyone who has a severely weakened immune system should not receive Flumist
13. 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).
14. 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.
15. History of blood dyscrasias, renal disease, or hemoglobinopathies requiring regular medical follow up or hospitalization during the preceding year.
16. 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.
17. Receipt of blood or blood products within the past 6 months or planned used during the study.
18. Medical or psychiatric condition or occupational responsibilities that preclude participant compliance with the protocol.
19. Receipt of an inactivated vaccine 14 days prior to study enrollment, or planned vaccinations prior to completion of last study visit (~ 28 days after study vaccination)
20. Receipt of a live, attenuated vaccine within 60 days prior to enrollment of planned vaccination prior to completion of last study visit (~ 28 days after study vaccination)
21. Need for allergy immunization (that cannot be postponed) during the study period.
22. History of Guillain-Barré syndrome
23. Pregnant or lactating woman
24. Use of investigational agents within 30 days prior to enrollment or planned use during the study.
25. 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.
26. 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

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

For all volunteers there will be 3 clinic visits at an outpatient clinic at Stanford - located in the Freidenrich Center for Translational Research (FCTR) at 800 Welch Road, Palo, CA 94304.

At Visit 1, we will review informed consent and your eligibility. You will receive the licensed seasonal influenza vaccination at the first clinic visit. This visit will require approximately 1 hour completing. The remaining 2 visits will take approximately 20-25 minutes each. 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.

Stanford U19 CCHI: Project 1. The role of CD4+ memory phenotype, memory, and effector T cells in vaccination and infection---Influenza-specific DR1501+ and DR0701+ T cells (under grant 'Adaptive Immune Responses and Repertoire in Influenza Vaccination and Infection'); SLVP031

The visit schedule is as follows:

Appointment Schedule:

VISIT (Sept-Dec.)	VISIT TYPE	DATE	TIME
Visit 1, Day 0 1 hour	Visit 1, Consent/ Blood draw/Vaccination		
Visit 2, Day 6-8 20-30 minutes	Visit 2, Clinic Visit/Blood draw		
Visit 3, (28±4 days after Visit 1) 20-30 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.

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