

**Eligibility Criteria and Visit Schedule (SLVP website link)  
2009 Novel H1N1 Flu Vaccine Trial**

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. To be considered, you must meet these requirements:

1. A male or non-pregnant female age 18 years of age or older.
2. If female and able to get pregnant (not surgically sterile via tubal ligation, bilateral oophorectomy or hysterectomy or who are not postmenopausal for  $\geq 1$  year), you must agree to practice adequate contraception that may include, but is not limited to, abstinence, monogamous relationship with vasectomized partner, barrier methods such as condoms, diaphragms, spermicides, intrauterine devices, and licensed hormonal methods during the study for at least 30 days following the last vaccination.
3. In good general health (as determined by vital signs, medical history to ensure any existing medical diagnoses or conditions are stable and not considered clinically significant, and a limited physical examination).
4. Have an ALT within normal range (ALT is a liver enzyme. This is a measure of your liver health and needs to be within normal limits for you to be eligible to participate in the study).
5. Able to understand and comply with study procedures
6. Able to understand the study consent and be willing to sign it.

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. The study doctors and nurses will also discuss this information in more detail during your screening visit.

1. You are allergic to eggs, because the inactivated virus for the H1N1 flu shot is grown in eggs and might contain a small amount of egg protein.
2. You have any other known allergies to other components in the vaccine (including gelatin, formaldehyde, octoxinol, thimerosal, and chicken protein) and/or squalene adjuvant.
3. You have ever had a severe reaction to a flu shot.

4. You received any live licensed vaccine within 4 weeks or inactivated licensed vaccine within 2 weeks before the H1N1 flu shot or plan to receive either type of vaccine within 21 days after the second H1N1 flu shot.
5. You took part in another 2009 H1N1 flu vaccine study in the past 2 years or have a history of new H1N1 2009 flu infection or treatment.
6. You received another experimental vaccine, medication, or blood product within 1 month before the H1N1 flu shot, or you expect to receive an experimental agent during the study period (before the final visit 12 months after the second H1N1 flu shot).
7. You are a woman and are pregnant or plan to get pregnant or are breastfeeding or are sexually active with men and not using an effective method of birth control (as discussed below) anytime from the beginning of the study until 30 days after the second H1N1 flu shot.
8. You have health conditions that weaken your body's ability to fight infections or are taking drugs like steroids that weaken your body's ability to fight infections. (Nasal and topical steroids are allowed.)
9. You have an illness or are receiving treatment that affects the way your immune system responds, or have received anticancer chemotherapy or radiation therapy within the last 36 months.
10. You have known active HIV, Hepatitis B or Hepatitis C infection or autoimmune hepatitis.
11. You have a history of drug and/or alcohol abuse in the past 5 years.
12. You have received immunoglobulin (gamma globulin) or another blood product within the past 3 months before the H1N1 flu shot.
13. You had a serious illness, including a fever with an oral temperature more than 100.4°F, within 1 week before you are scheduled to receive the H1N1 flu shot.
14. You have an acute or chronic medical condition that, in the opinion of the investigator, would make vaccination unsafe for you or would interfere with the evaluation of your responses.
15. You have unstable psychiatric disease.
16. You have a history of Guillain-Barré Syndrome (GBS).
17. You plan to travel outside of North America in the time between the first H1N1 flu shot and 42 days following the first H1N1 flu shot.
18. There are some medications that you should not take while in this study. The study staff will discuss these with you.

### **Scheduling Appointments:**

### **III. Study Visits/ Schedule**

There will be 7-8 clinic visits and 4 telephone contacts that will take place over 13 months after enrollment.

You will receive the H1N1 influenza vaccination after enrollment at Visit 1. There will be a blood draw at each clinic visit.

The screening visit may be combined with Visit 1 and will require approximately 1 -1½ hours to complete. Visits 1 and 3 will require approximately 1 – 1 ½ hour each. The remaining visits will take approximately 20-30 minutes each. The phone call will require no more than 15 minutes.

The visit schedule is as follows:

<b>Window</b>	<b>Visit</b>	<b>Date</b>	<b>Time</b>
Screening Visit (May be combined with Visit 1) Day 0 to -28  Visit 1, Day 0	Screening Visit in Clinic: Consent/Eligibility/Blood draw  Visit 1: Clinic Visit. Eligibility/ Vaccination #1 / Blood draw		
Visit 1a, Day 2 Window: Day 1 to 3	Phone Call		
Visit 2, Day 8-10	Visit 2: Clinic Visit. Review health status/ Blood draw		
Visit 3, Day 21 (+3)	Visit 3: Clinic Visit. Vaccination #2 / Blood draw		
Visit 3a, Day 1-3 after Vacc #2	Phone Call		
Visit 4, Day 8-10 after Vacc #2	Visit 4: Clinic Visit. Review health status/ Blood draw		
Visit 5, Day 21-24 after Vacc #2	Visit 5: Clinic Visit. Review health status/ Blood draw		
Visit 6, Day 60 ( $\pm 7$ ) after Vacc #2	Phone Call		
Visit 7, Day 120 ( $\pm 14$ ) after Vacc #2	Phone Call		
Visit 8, Day 180 ( $\pm 14$ ) after Vacc #2	Clinic Visit. Review health status/ Blood draw		
Visit 9, Day 365 ( $\pm 14$ ) after Vacc#2	Clinic Visit. Review health status/ Blood draw		

Thank you for your interest in our research. **Please contact the study staff at (650) 498-7284** if you have any questions. We look forward to talking with you.