






## A Phase II Study in Healthy Adult and Elderly Populations to Assess the Safety and Immunogenicity of a Sanofi Pasteur H1N1 Influenza Vaccine Administered at Different Dose Levels Given With and Without GlaxoSmithKline AS03 Adjuvant

-  Men and women
-  Questionnaires
-  Drug study
-  Injections
-  Blood draws

**Purpose:** The 2009 H1N1 influenza virus (formerly known as “swine flu”) is a new flu virus that first caused illness in Mexico and the United States in March and April, 2009. This study will test an investigational influenza vaccine that contains the 2009 H1N1 flu strain. This study’s vaccine is investigational because it has not been licensed (approved) by the U.S. Food and Drug Administration (FDA).

The purpose of the study is to evaluate the immune responses and reactions to three different strengths of a 2009 H1N1 influenza vaccine with and without an adjuvant. This study is sponsored by National Institutes of Health.

Participants in the study will be assigned by chance (like flipping a coin) to one of five study groups. Participants will receive one of three strengths (3.75 micrograms, 7.5 micrograms, or 15 micrograms) of the 2009 H1N1 flu vaccine, with or without adjuvant. All participants will receive two injections of the vaccine, with the second vaccination given 21 days after the first. Participants will come to the clinic for a total of 7 visits and receive two study vaccinations. Study staff members will also call participants by phone 4 times to ask about any side effects to the vaccine and collect other health information. Participation in this study will last about one year.

<i>We need:</i>	<i>We provide:</i>
<ul style="list-style-type: none"><li>• Men and women, 25 years or age or older</li><li>• In good health</li><li>• Women of child-bearing potential must not be pregnant and must agree to practice adequate contraception for the entire study period</li></ul>	<ul style="list-style-type: none"><li>• \$30 for screening visit</li><li>• \$60.00 per clinic visit after enrollment (total of \$490 for completing all visits)</li></ul>

### *Exclusion Criteria:*

- Have received any licensed vaccines within 2-4 weeks prior to the first study vaccine and not planning to receive any licensed vaccines for 21 days after your second study vaccine. This includes the seasonal influenza vaccine.
- Have participated in an H1N1 influenza vaccine study or have a history of H1N1 influenza infection
- Plan to travel outside North America, including travel to Hawaii or Alaska
- Are a healthcare worker or emergency medical services worker
- Live with or care for children younger than 6 months of age



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