# H1N1 Antibody Titers in Screening Healthy Individuals For Plasma Donation

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# BACKGROUND

The April 2009 outbreak of a novel strain of influenza A/H1N1 ("swine flu") is currently causing a worrisome pandemic of influenza A. Originating in Mexico, this atypical virus is the product of natural genetic reassortment of influenza virus from human beings, swine and bird.[1] While the 2009 H1N1 activity declined after October, 2009 human illness with 2009 H1N1 is ongoing in the United States. From April 23, 2009, through April 10, 2010, it is estimated that pandemic (H1N1) 2009 virus caused ≈61 million cases of influenza (range 43–89 million cases), ≈270,000 related hospitalizations (range 195,000–403,000 hospitalizations), and ≈12,500 deaths (range 8,900–18,300 deaths) in the United States.[2] The virus was, in fact, the predominant influenza virus in circulation during the 2009-2010 flu season, and experts do anticipate further waves of flu activity during the 2011 winter and beyond.[3] Adding to this concern is the fact that seasonal flu vaccines prove ineffective against the virus, and a limited supply of H1N1 vaccines prevents vaccination of all individuals. Indeed, with present technology, the current worldwide production capacity for influenza vaccine is able to cover less than 5% of the world's population.[4] Current recommended treatment for all people with suspected or confirmed influenza includes the influenza antiviral drugs, principally the neuraminidase-inhibiting influenza antiviral drugs, oseltamivir and zanamivir.[5] However clinical observation of oseltamivir drug resistance is a concern, and both drugs' resistance to H1N1 is possible due to etiologies.[6] These limited therapeutic options for influenza, along with significant morbidity and mortality rates despite treatment, demand an urgent need be placed on additional therapeutics for the treatment of severe H1N1 pneumonia.

In response to this need is the objective of the NIAID Influenza Research Collaboration and Protocol: IRC 001. This protocol is concerned with the collection of anti-influenza A H1N1 immune plasma from human volunteers with a high titer anti-influenza H1N1 2009 antibody titer (either recovering survivors or H1N1 vaccine recipients). Following testing of the collected plasma for potential pathogens, it may be used as therapeutic plasma, and/or it may be used for manufacturing of high titer anti-H1N1 intravenous immune globulin (IVIG). Both options would support clinical trials aimed at developing additional therapeutics for H1N1 infection. A secondary objective of this protocol is to further define the immune response to H1N1 (infection and/or vaccine) in humans.

## OBJECTIVES

1) Collection of high titer anti-influenza A H1N1 immune plasma from volunteers, both convalescent survivors and H1N1 vaccine recipients.
2) Determination of mean, median and range of H1N1 antibody titer of individuals screened.
3) Determination of percentage of individuals who qualify for plasma donation.

# METHODS

**Recruitment**

Interested community members aged 18-60 yrs. who had received an H1N1 vaccine or reported recovering from an influenza-like-illness within the last 12 months are invited to the Johns Hopkins Donor Center for screening.

**Screening Visit I**

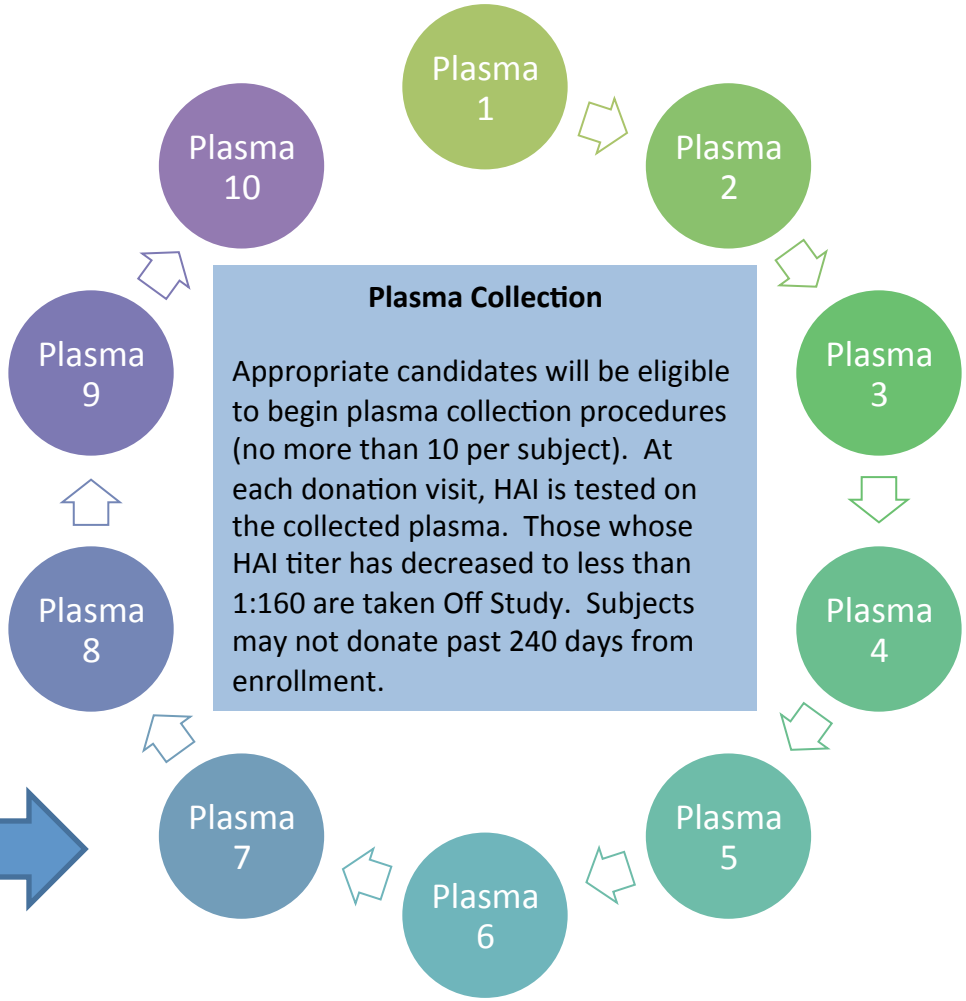
Includes:
Review and signing of the informed consent by subjects, as well as review of the inclusion/exclusion criteria to determine that subjects have appropriate clinical and medical history parameters.

Subjects who meet these parameters undergo a blood draw for determination of anti-influenza A/ H1N1 2009 hemagglutination inhibition titers (HAI).

Screening Visit II

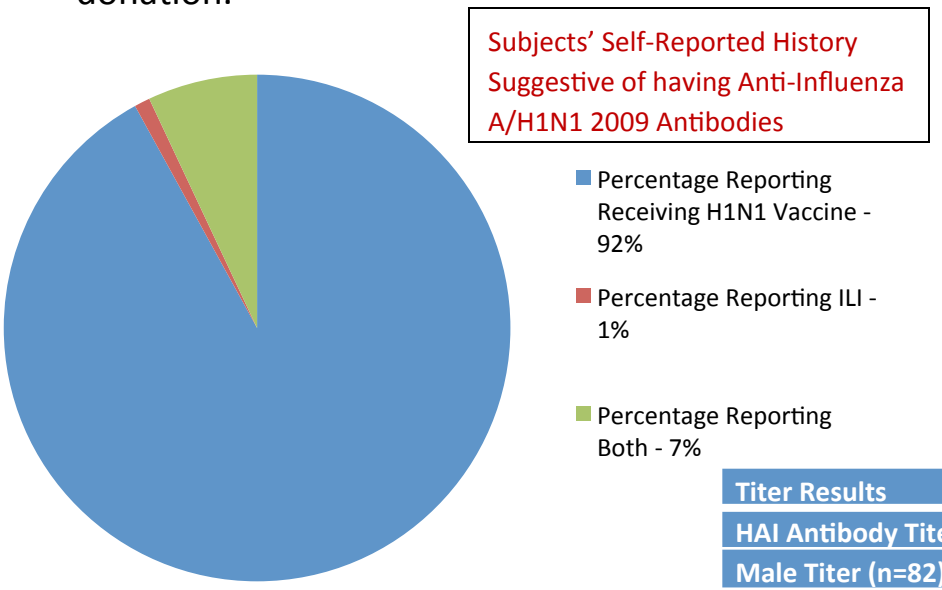
Includes subjects with an anti-influenza A/H1N1 2009 HAI of at least **1:160.**

A second blood draw for standard blood donor testing and questions regarding suitability as a plasma donor are performed.



# RESULTS

- From May 2010 to September 2011, 240 individuals (82 men, 158 women) were tested for H1N1 titer.
- Of 240 individuals tested, 50% (119/240) had a titer of ≥1:160 of whom 43% (51/119) qualified for plasma donation.
- Mean age was 33 yrs. (range 18 to 60 yrs.)
- 19% of women vs. 25% of men screened qualified for plasma donation.
- The mean, median, and range of H1N1 antibody titer for all individuals tested at screening was 1:99, 1:103, and 1:5 to 1:1280, respectively.
- Of those with a titer of ≥1:160, the most common reason for deferral was a low hematocrit or hemoglobin.
- 75% (38) of the 51 individuals who met the requirements for plasma donation have proceeded to donation.




| Titer Results | Mean |
|---|---|
| HAI Antibody Titer (n=240) | 1:99 |
| Male Titer (n=82) | 1:104 |
| Female Titer (n=158) | 1:197 |
| Subject Titer <35 yrs. (n=132) | 1:132 |
| Subject Titer >35 yrs. (n=108) | 1:70 |

## CONCLUSIONS

Approximately, half of individuals who received an H1N1 vaccine or had an ILI in the last 12 months had an H1N1 HAI titer ≥1:160 and, of those, 43% were eligible to proceed to plasma donation.

## ACKNOWLEDGEMENTS

- National Institutes of Allergy and Infectious Diseases (NIAID)
- IRC 001 Protocol Team
- Johns Hopkins Blood Bank
- Johns Hopkins Hemapheresis and Transfusion Center (HATS)

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