



Approval Date: December 5, 2018
Approved Consent Version No.#1
PI Name: Kawsar Talaat
IRB No. 00008909

**JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH
INFORMED CONSENT DOCUMENT**

Study Title: **An Exploration of a Prime-Boost Approach for Universal Influenza Vaccination: Immunogenicity and Safety Study of Inactivated Subunit H5N1 Influenza Vaccine in Prior Recipients of Live Attenuated H2N2, H6N1 and H9N2 Influenza Vaccines and in H5N1 and Live Attenuated Vaccine Naïve Individuals**

Sponsor: **National Institute of Allergy and Infectious Diseases (NIAID)**

PRINCIPAL INVESTIGATOR: Kawsar Talaat, MD

IRB Protocol No.: **00008909**

Consent Version and Date: Version 1.1, dated 19 November 2018

What You Should Know About This Research Project

- You are being asked to join a research study.
- This informed consent document explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not understand.
- Do not sign this document unless all your questions about the research study have been answered to your satisfaction.
- You are a volunteer. You can choose not to participate and if you choose to participate, you may quit at any time. There will be no penalty if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might cause you to change your mind about participating in study.
- A description of this clinical trial will be available on <http://www.ClinicalTrials.gov> as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.
- If you would like to review the information for this study, or a summary of results, ask the study doctor for the ClinicalTrials.gov study registration number.

Purpose of the Research Project

Researchers are working to develop a better flu vaccine - one that is capable of providing long-lasting protection against many strains of the flu virus even as they change over time. Such a vaccine may get rid



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of the need for the seasonal flu vaccine each year and could provide protection against newly emerging flu strains, including those that could cause a flu pandemic.

The purpose of this research study is to test a potential approach to inducing strong, long lasting protection against a broad range of flu viruses. We want to do this by triggering a special kind of immune (germ-fighting) response, called stalk antibodies.

Background Information

Influenza (flu) is a potentially serious infection that can lead to hospitalization and sometimes even death. Influenza infection sickens some people more than others depending on age and health status. Every year, millions of people get the flu, hundreds of thousands of people are hospitalized and tens of thousands of people die from flu-related causes.

Circulating flu viruses vary season to season and all influenza viruses undergo frequent genetic changes. Current influenza vaccines stimulate a protective immune response only to the strains in the vaccine. These immune responses may not protect us from illness caused by new or different strains. This is why flu vaccines must be updated each year and why they don't always prevent the flu.

Rationale

Surface proteins on influenza viruses consist of two distinct parts – a head and a stalk. Current vaccines induce antibodies (germ fighters) that attack the head of the surface proteins because the head is the easiest target. The head of the surface protein has more changes over time than the stalk. Researchers are working on ways to boost stalk specific antibodies because they have the potential to protect across different influenza types and strains.

By conducting this study, researchers hope to determine if vaccination with a live attenuated vaccine followed by an inactivated vaccine bearing a different head but similar stalk will boost the stalk antibody response.

This study will examine if giving one type of flu vaccine to people who had previously received other, live attenuated vaccines will trigger more stalk antibodies than the vaccine triggers in people who did not receive those vaccines.

Study Participants

We will recall up to 15 prior research subjects who received 2 doses of H2N2, H6N1 or H9N2 pandemic live attenuated vaccines (pLAIVs), in the past who agreed to let us contact them for future studies, and administer 1 dose of inactivated H5N1 vaccine.

A control group of up to 20 subjects who have never received a pandemic live attenuated vaccine will be recruited from the general public to serve as a control group and will also receive 1 dose of the inactivated H5N1 vaccine.



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Study Schedule

There are 7 study visits – 1 vaccination/enrollment visit (approximately 2 hours) and 6 follow up visits (approximately 30 – 45 minutes each) for safety at 7, 14, 28, 56, 90, 360 days after vaccination

Treatment Assignment

All subjects enrolled in the study will receive 1 dose of H5N1 influenza virus vaccine.

Information about the Investigational Vaccine

Monovalent Influenza Subvirion Vaccine (H5N1) is an inactivated (killed) influenza vaccine. This H5N1 vaccine has been tested in hundreds of people and has been shown to be safe and well tolerated. By itself, it can induce an immune (germ-fighting) response when given in very high doses (90 micrograms (μg)- 4 times the usual influenza vaccine dose). The U.S. Food and Drug Administration (FDA) approved this vaccine at 2 doses of 90 μg , for immunization of persons 18-64 years of age at increased risk of exposure to the H5N1 influenza virus subtype contained in the vaccine. Sanofi Pasteur Inc. manufactures the vaccine.

For this research study, we will administer a single, smaller dose of the vaccine (45 μg) to see if the earlier vaccination with the pLAIV H2N2, H6N1 or H9N2 improves the stalk immune response to H5N1 vaccine. The dose, not the vaccine itself, is experimental. This dose is investigational (experimental) because it is lower than dose approved by the US FDA.

The vaccine for this clinical trial is from a lot prepared specifically for investigational use. The vaccine will be provided by the Biomedical Advanced Research and Development Authority (BARDA), U.S. Department of Health and Human Services.

Why You are Being Asked to Participate

Up to 35 healthy, adult volunteers are needed for a study to learn more about a prime-boost approach to universal influenza vaccination. Each volunteer will be given 1 dose of the H5N1 vaccine. Some of you are being asked to participate because you previously received 2 doses of an H9N2, H2N2 or H6N1 live-attenuated influenza vaccine as a participant in an earlier CIR vaccine study. Others of you are being asked to participate as part of a control group that has never received a pLAIV.

Basic Eligibility Requirements



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You participated in our IRB approved general screening study and were found to meet the following basic eligibility requirements.

- You are 18-60 years old.
- You are not pregnant or breast-feeding, and you are not at risk of becoming pregnant during the study for reasons such as one or more of the following:
 - You are male, or if you are female there is:
 - No possibility for pregnancy because of menopause (one year without menses) or because you have had surgery to remove your uterus and/or ovaries or tie your tubes (tubal ligation),
Or
 - You have reported absolute abstinence from heterosexual intercourse as a matter of normal preferred lifestyle;
Or
 - You agree to use effective birth control methods beginning at least one month prior to vaccination, and continuing with 'per label/fully effective use' for the chosen method for the duration of the study, from amongst these:
 - pharmacologic/hormonal contraceptives, including oral, parenteral, subcutaneous, and transcutaneous delivery; condoms with spermicide;
 - diaphragm with spermicide; intrauterine device
- The medical history you gave us and your blood and urine or serum pregnancy tests indicate that you are in good health and not pregnant or breastfeeding.
- You are available for the duration of the clinical trial or 12 months.
- You agree to make sure we have a way to contact you for the duration of the study including but not limited to:
 - Telephone call
 - Text message
 - Email message
 - Card mailed by US Postal Service
 - Via a friend or relative if we cannot reach you directly
- You agree to allow for storage and testing of your laboratory specimens for future research.
- You have never had a life-threatening reaction to a prior influenza vaccination.
- You do not have an allergy to thimerosal.
- You have read, agreed to comply with, and signed the **Code of Conduct**.
- You received the 2018-19 flu vaccine at least 30 days prior to study enrollment or you do not want to be vaccinated at this time and are agreeing to defer receipt of the 2018-19 flu vaccine. Please check the boxes next to the statement(s) describing your status with respect to receipt of flu vaccine for the 2018-2019 flu season:

You have already been vaccinated –

- The study nurse or nurse practitioner offered no cost vaccination to you at your initial screening visit and you accepted

OR



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- You reported prior receipt of the 2018-19 flu vaccine at your doctor's office, clinic or urgent care center, through school or work, or other setting.

You have not been vaccinated this flu season and do not want to be vaccinated –

- The study nurse or nurse practitioner offered no cost flu vaccination to you at your initial screening visit and you declined

AND

- You have agreed *not* to get the seasonal flu vaccine during the time frame spanning 1 month prior to enrolling in this study and receiving the investigational vaccine until you complete the Day 90 follow up visit.

AND

- You have been counseled as to the benefits of annual seasonal flu vaccination and understand that declining or delaying flu vaccine increases your risk of illness due to seasonal influenza virus.

You have the option of requesting the flu vaccine at no cost to you, today or any day prior to enrollment. We will simply defer your enrollment visit and administration of study vaccine for 30 days.

The Investigational vaccine will not protect you from getting sick with the seasonal flu.

Now that you have met basic eligibility by participating in a general screening study, we have asked you to participate in a screening and consent visit for the **Phase 1 Exploration of a Prime-Boost Approach for Universal Influenza Vaccination that will look at the safety and germ fighting ability of an H5N1 Influenza vaccine in people who have documented proof of having previously received an H2N2, H6N1 or H9N2 Influenza vaccine and those who have not.** Today, we will provide you with a complete description of the study and are asking you to:

- Read this consent for participation in the vaccine trial carefully and thoroughly.
- Show that you understand this research study and your part in it by completing a comprehension assessment with a score of 70% or better and verbalize understanding of all questions answered incorrectly.
- Acknowledge that your questions about the study have been answered to your satisfaction and that your consent to participate in the study is given freely.
- Sign this document indicating your consent to participate in this study and comply with study requirements.
- Complete a physical exam
- Have laboratory tests including:
 - HIV test: State law requires that the results of positive tests for HIV be reported to a local health agency.
 - Hepatitis B and hepatitis C tests: State law requires that the results of positive tests for hepatitis be reported to a local health agency.
 - If any screening tests are abnormal, the study staff will tell you. You will be referred to your primary medical provider for follow-up care.
- Participate in a review to determine if you are eligible for the study.



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- Sign a medical records release form for the purpose of obtaining medical records if you are treated for an illness or injury at a doctor's office, ER, or hospital during study participation.

Key Study Procedures

We want to enroll up to 35 volunteers who are willing to receive 1 dose of the H5N1 investigational vaccine. Up to 15 of the volunteers will have previously participated in another Influenza vaccine research study and received either an H2N2, H6N1 or H9N2 vaccination.

Eligibility Determination

For vaccine studies we need healthy adults with healthy immune systems. The information you shared with us during the screening study - your laboratory test results, self reported medical history, and physical exams are the basis for making decisions about eligibility. Your safety as a study participant depends in part on the information you are willing to share with us about your health.

Vaccination

The H5N1 vaccine in this study will be administered as a shot in the muscle of the upper arm (deltoid muscle). Everyone will receive the H5N1 vaccine once. After you are vaccinated, we will ask you to stay in the clinic for at least 30 minutes for observation; at the end of that time, we will evaluate your injection site and repeat your vital signs.

Post Vaccination Follow up

After you are vaccinated, we will ask you to return to the research clinic for six follow up visits for safety and research assessments. Each day you return to the unit for an outpatient follow up visit, you will be evaluated and have your blood drawn. The total duration of study participation is approximately 360 days from the day you are vaccinated.

Here is a schedule of what you will be asked to do at each outpatient visit if you agree to be part of this study.

Day 0 (approximately 2 hours)

- Have your vital signs taken
- You will have a physical exam.
- Have blood drawn. (~1/2 cup)
- If you are female, you will have a urine pregnancy test.
- Receive an injection in the deltoid muscle of located in the upper most part of your arm
- The medical study staff will observe you for the first 30 minutes after vaccination for signs of an allergic reaction.
- We will evaluate your injection site and repeat your vital signs.

Day 7 (approximately 30-45 minutes)

- You will answer question about any acute complaints over the past 7 days



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- Have your vital signs taken
- Have your injection site evaluated
- You may have a physical exam, if indicated
- Have blood drawn (~5 tablespoons)

Days 14 (approximately 30-45 minutes)

- You will be asked questions about your medical history since last visit
- If female, you will be provided with pregnancy prevention counseling
- Have your vital signs taken
- You may have a physical exam, if indicated
- Have blood drawn to measure your immune response (~4 tablespoons)

Day 28 (approximately 30-45 minutes)

- You will be asked questions about your medical history since last visit
- You may have a physical exam, if indicated
- If you are female you will have a urine pregnancy test.
- Have blood drawn to measure your immune response (~7 tablespoons)

Day 56 (approximately 30-45 minutes)

- You will be asked questions about your medical history since last visit
- Have blood drawn to measure your immune response (~4 tablespoons)

Day 90 (approximately 30-45 minutes)

- You will be asked questions about your medical history since last visit
- Have blood drawn to measure your immune response (~1/2 cup)
- If you are female you will have a urine pregnancy test.

Day 360 (approximately 30-45 minutes)

- You will be asked questions about your medical history since last visit
- Have blood drawn to measure your immune response (~1/2 cup)

Outpatient Follow-up

For your safety, and for research purposes, it is very important that you complete all of your follow up visits on time.

As described above, your outpatient follow up visits will be brief and will include the following procedures:

- Research staff will ask you questions about your health, obtain a blood sample (up to 8 tablespoons).
- Obtain vital signs.
- You may have a physical exam, and if female, a pregnancy test.

Risks/Discomforts



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The risks of study participation that are described in this document are based on the assumption that you are in good health. Risks may be greater for people who have current or past history of certain medical conditions. In this study, there are risks related to the investigational vaccine, and risks related to study procedures.

Risks related to the Investigational Vaccine

This H5N1 vaccine has been tested in hundreds of people so far. It has been shown to be generally safe and well tolerated.

We can tell you what we think the risks will be based on research in animals and human trials.

In previous studies with this vaccine, mild pain at the injection site was the most common side effect of the vaccine.

- You may experience local site reactions redness, swelling, tenderness, itching or hardness at the injection site.
- You may have pain with moving your arm for several days or swollen lymph nodes under your arm.
- You may have fever, chills, headache, tiredness, a general ill feeling, muscle or joint aches, nausea, vomiting, or loss of appetite requiring several doses of medication such as Tylenol™ or Motrin™.

Allergic reactions such as rash, hives, asthma and anaphylaxis are a possibility whenever you take something new into your body. Anaphylaxis is a rapid, severe allergic reaction that could result in death. The study medical staff will watch you carefully for 30 minutes after you are vaccinated. We will treat you immediately for any signs of an allergic reaction.

There may be other side effects that we cannot anticipate given current knowledge and understanding. We will let you know if there are any unanticipated side effects of this study vaccine and if new information becomes available that may impact your decision to continue in the study.

Women

The effects of the vaccine on the unborn fetus and breast-feeding infant are not known. Women who are pregnant or breast-feeding will not be eligible to participate in the study. All women who can become pregnant must agree to consistent use an effective birth control method (see eligibility criteria). Ask the study doctor for information about effective birth control if you are not satisfied with your current method. We may be able to refer you to a practitioner who can help you choose a method that is right for you. A pregnancy test will be done during the screening visit and on the day of vaccination. This test must be negative for the staff to give you the vaccine. A pregnancy test will also be done on several visits after you receive the vaccine.

Please tell the study staff right away if you become pregnant. We will ask you to come in for your regularly study visits or ask you to agree to let us keep checking on you until the end of your pregnancy. You will be



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asked to sign a medical release form so that we can learn about your pregnancy and your baby's health at birth.

Risks Associated with Study Procedures

Blood drawing – can cause pain, bruising, bleeding, and rarely, infection at the puncture site. Sometimes, drawing blood can cause people to feel lightheaded or to faint. Making sure you are well hydrated prior to your blood draw makes it easier to obtain an adequate sample.

Nasal wash – If you experience cold symptoms we will ask you to provide a nasal secretion sample. This can cause mild discomfort and, very rarely, a nosebleed. This is like getting salt water in your nose when swimming in the ocean.

Do Not Participate in Other Studies During This Study

Please *do not* participate in other studies or take other investigational drugs until you complete the Day 90 follow up visit. Because this is an experimental vaccine study, we do not know what will happen if you take another experimental drug or vaccine at the same time. You may be at a higher risk of serious health consequences if you take more than one investigational drug at a time.

Tell Us if You are Taking any Other Medications.

We are looking at your immune (germ fighting) response to the vaccine. It is important for you to let the study doctor know if you receive any other vaccines, blood or blood products, steroids or other medication outside the study whether they are prescribed by a doctor or obtained over the counter. Other vaccines, medication or treatments might interfere with the germ fighting ability you develop in response to the study vaccine.

Tell Us If You Are Injured Or Become Ill

A study doctor will be available by phone at all times during the study. A study nurse is also available by phone at all times if you have any questions. Dr. Kawsar Talaat at 410-502-9627, 410-336-9164 (24 hours), or Katie Chang, RN 410-627-8079 (24 hours).

We ask that you notify the study staff if you become ill at any time while you are a study participant even if you do not think it is related to the study drug. If you report respiratory symptoms we will ask you to provide a nasal secretion sample to screen for a variety of respiratory viruses including flu. If you have the flu or other respiratory virus, the study nurse, or doctor will make recommendations for over the counter symptom management or refer you to your PCP, clinic or urgent care center as indicated.

If you report an illness or injury during study participation necessitating a doctor's office visit, ER visit or hospitalization, we will request medical records pertaining to that medical event. Similarly, information about your participation in this research study may be released to your medical provider for safety and care planning purposes.



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New Findings

We will let you know if we learn anything new that might change your decision to be in this study. If new findings lead to changes in our research plan, you may be asked to repeat the informed consent process to insure that you are aware of any changes impacting your participation in the study and confirm that you agree to them.

Benefits

There is no direct benefit to you participating in this research study. If you are included in the study, you will get physical assessments and laboratory tests as part of the study procedures. These results will be available for you if you would like them. If any health problems are identified during the course of the study, you will be referred for care. This does not take the place of regular visits to your health care provider.

Other people may benefit from the results of this study at some point in the future as a result of your willingness to participate.

Compensation

You will be paid a total of \$80.00 for screening for the study if you satisfy all the study requirements and are enrolled in the study and receive the investigational vaccine. You will be paid \$125.00 for the vaccination visit and \$80.00 for each outpatient visit you complete. You will only be paid for the visits you complete. You will be paid a \$250.00 bonus for complying with all study requirements and completing all scheduled visits on time. If you do not complete all study procedures, follow study rules, or complete all visits, your compensation will be reduced by the missed visit amount and some or all of your bonus.

In addition to the compensation described above, if you participated in a previous H2N2, H6N1 or H9N2 Influenza study at the Center for immunization Research and are enrolled, vaccinated and complete all study visits through Day 28, you will receive a \$250.00 bonus upon completion of the Day 28 follow up visit.

To comply with federal law, this payment will be reported as income to the internal revenue service (IRS).

If you choose to withdraw before the study is completed, you will only receive payment for the number of visits that you have completed.

If the study is stopped before you have finished all of the visits, you will receive payment for the number of visits that you have completed, plus a portion of the bonus.

Protecting Data Confidentiality

We will take the following steps to protect the safety of your research data and the information you share with us while you are a study participant:

- Your study data and biological samples will be identified by a unique study ID, not your name.
- Your personal information will be stored in a secure location that is separate from your study data.



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- Your study data will be stored in locked cabinets and/or password protected computer files.

Protecting Volunteer Privacy During Data Collection

All volunteer assessments and study procedures will take place in private assessment and treatment rooms.

Alternatives to Procedures or Treatments

This is not a treatment study. The study drug is not a cure for any pre-existing health conditions that you have reported. You are a healthy adult. You may choose not to participate in this study.

Biological Specimens

Stored Samples – Past Study

If you have previously participated in the H2N2, H6N1 or H9N2 pLAIV studies, we stored any left over blood samples we had from those studies. We ask that you allow us to test some of your samples that we have stored from those studies. We want to compare the stalk antibodies you made then to what you can make now.

Stored samples – Current Study

The biological specimens you give to us during this study are important to science. Any unused blood will be stored once this study is completed. You will not own your biological samples after you give them to the study. You will not receive any financial benefit from any product or idea created by the investigators using the data or biological samples collected from you.

Your blood may be used for future research to learn more about Influenza vaccines and immune response to vaccines. Samples may be stored at the CIR and the Laboratory of Infectious Diseases of the NIH. These samples will be used only for research. They will not be sold or used to make products for sale. Agreeing to sample storage is a requirement of study participation. You should not join the study if you do not want your samples to be stored.

There will be no human genetic tests done on your blood samples. The samples will be coded so that they cannot be linked to you as the source. Reports about research done with your samples will not be put in your health record. There will be no direct benefit to you from any future research use of your samples but we may learn more about how to prevent and treat illness caused by Influenza virus. Results from future research using your samples may be presented in publications and meetings, but your will not be identified as a study participant.



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Cost of Participation in the Study

There are no expected costs to you for being in this study. Ask your study doctor to discuss the costs of treating possible side effects. Otherwise, you might have unexpected expenses from being in this study.

What Happens if you Leave the Study Early?

Your participation in this study is voluntary. You may decide not to participate and you may leave the study at any time. If you decide to withdraw from the study soon after you are vaccinated, the study doctor may ask you to return to clinic for evaluation for safety reasons.

Your decision not to participate or to withdraw from the study will not result in any penalty or loss of benefits to which you are entitled. Your decision will not jeopardize present or future employment or educational opportunities at Johns Hopkins University, nor impact your medical care at any Johns Hopkins Medical facility.

If you decide to leave the study, your unused samples will be destroyed. You should ask the study doctor listed below any questions you may have about this research study. You may ask questions in the future if you do not understand something that is being done.

You may be withdrawn from the study at any time by the study doctor or the sponsor without your consent if:

- The study sponsor decides to stop or cancel the study for any reason
- The study staff or the study sponsor decides to discontinue your participation for any reason
- The staff or your study doctor feels that staying in the study is harmful to your health
- You do not follow instructions from the staff or do not keep appointments
- The FDA or JHSPH Office for Research Subjects feel the study should be stopped
- If new information becomes available regarding the safety of the vaccine
- You do not consent to continue in the study after being told of changes in the research that may affect you

Sharing Your Health Information with Others

Your name, birth date, and social security number are not given to anyone unless required by law. All of the information you give us during this study will be kept in locked cabinets and/or in password-protected computer files. The only people who will have access to your information are those involved in the study.

There will be people working on the study who need to see your research information. These people may include the researchers, study and lab personnel, and other research study staff.

Others who may see your information are the groups of people who make sure that the study is conducted safely, ethically, and according to federal regulations. These groups are:

- The Johns Hopkins University Bloomberg School of Public Health
- Audit and Compliance Officers and Legal Counsel



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- The Office for Human Research Protections (the government agency that makes sure that we are conducting the research as planned)
- The US Food and Drug Administration (FDA) and similar regulatory agencies
- The sponsor (National Institute of Allergy and Infectious Disease [NIAID], a branch of the National Institutes of Health [NIH]) of the study and the people the sponsor may contract with for the study
- The Medical Monitor
- The Maryland State Health Department

These people are required to keep your identity private. Maryland State Law requires us to report some diseases and information about child abuse. If reported, this information may not remain confidential. Otherwise, the information that identifies you will not be given out to people not working on the study, unless you give us permission.

What we learn from the research may be published in a medical journal or used for teaching. The information shared will not be linked to you as the source. You will not be identified as a study participant.

Certificate of Confidentiality

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means. It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Medical Monitor

A medical monitor is a physician who is not involved in the running of the study, but who has agreed to help protect your safety. This physician will review the safety data from this study regularly, and will give advice to the investigator if they are concerned about any of the safety information.

Conflict of Interest

This protocol may have investigators who are not NIH employees. Non-NIH investigators are expected to adhere to the principles of the Protocol Review Guide but are not required to report their personal financial holdings to the NIH. Dr. Talaat is a faculty member at Johns Hopkins University.

Payment of Treatment Costs for Injury or Illness From Study Participation

A study doctor will be available at all times while you are in the study to check on you and treat you for any short-term medical care need resulting from your participation in this research study. This short-term



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medical care will be paid for through our contract with NIH. Short-term medical care will be given at a facility determined by JHU and NIH.

In general, the JHU, Johns Hopkins Hospital, the NIH, or the Federal Government will not routinely provide long-term medical care or financial payment for research-related injuries. At your request, your insurance company will be billed for payment of any such treatment or hospitalization. Check with your insurance company before you start this study to find out what your insurance company will pay for. The JHU, the Johns Hopkins Hospital, the Johns Hopkins Bayview Medical Center, the NIH, and the Federal Government do not have a program to pay you if you are injured or have other bad effects that are not the fault of the study doctors. However, you do have the right to seek legal remedy if you believe that your injury justifies such action.

Clinical Trial Registration

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov> as required by US Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who Do I Call if I Have Questions or Problems?

If you have any questions about your participation in this study, if you have questions, concerns or complaints about the research or if, at any time, you feel you have experienced a research-related injury or a reaction to the study vaccine, contact:

Dr. Kawsar Talaat, Principal Investigator (study doctor) at 410-502-9627 or 410-336-9164 (24 hours),

or

Katie Chang, BS, RN, CCRP (study coordinator) 410-627-8079 (24 hours).

Call or contact the Johns Hopkins Bloomberg School of Public Health IRB Office if you have questions about your rights as a study participant. Contact the IRB if you feel you have not been treated fairly or if you have other concerns. The IRB contact information is:

Address: Johns Hopkins Bloomberg School of Public Health
615 N. Wolfe Street, Suite E1100
Baltimore, MD 21205
Telephone: 410-955-3193
Toll Free: 1-888-262-3242
E-mail: JHSPH.irboffice@jhu.edu

Your signature on this form means:



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- You have been informed about this study's purpose, procedures, possible benefits and risks.
- You agree to the storage of your bio specimens for use in future studies on influenza vaccine and immune response to vaccines
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this study.

Print name of Adult Participant

Signature of Adult Participant

Date

Time

Print name of Person Obtaining
Consent

Signature of Person Obtaining
Consent

Date

Time

Give one copy to the participant and keep one copy in study records.