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JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

INFORMED CONSENT DOCUMENT

Study Title:	**Phase 1 Evaluation of a Live-Attenuated Human Parainfluenza Virus Type 3 Vectored Vaccine Candidate Expressing Ebolavirus Zaire Glycoprotein as the Sole Envelope Glycoprotein**
Principal Investigator:	**Kawsar Talaat, M.D.**
IRB Protocol No.:	**00008107**
PI Version Date:	Version 2.1 1 May 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 the study.
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. 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.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

Purpose of the Research Project

The purpose of this research project is to learn about the safety and immune (germ-fighting) response in healthy adults to an experimental vaccine to protect against Ebolavirus disease (EVD). An experimental vaccine is one that has not been approved for marketing or sale by the U.S. Food and Drug Administration (FDA). The FDA is allowing the use of this Ebola vaccine in this study. This Ebola vaccine candidate has never been administered to humans.

Background Information

The Ebola viruses are among the most deadly viruses known. The first EVD outbreaks occurred in remote villages in central Africa, near tropical rainforests. In 2014 and 2015, you may have heard news reports of the largest Ebola epidemic in history affecting multiple countries in West Africa, with

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outbreaks occurring in major urban areas as well as rural areas. This epidemic highlighted the urgent need for safe, cheap, and easy to administer vaccines to protect against the disease.

Information about the Experimental Vaccine Product
The Laboratory of Infectious Diseases (LID) at the National Institute of Allergy and Infectious Diseases (NIAID), within the National Institutes of Health (NIH), has a long history of vaccine development in partnership with the Center for Immunization Research (CIR) at Johns Hopkins Bloomberg School of Public Health (JHSPH). LID scientists have been working on developing an Ebola vaccine for administration as a nose spray – a needle-free alternative to injectable vaccines. First-in-human trials of a nasal spray vaccine to protect against EVD were initiated at the CIR in 2015. In animal studies, including monkeys, the vaccine we are testing in this study was well tolerated and did not appear to cause serious side effects or discomfort.

The vaccine being tested in this study (**HPIV3/ΔHNF/EbovZ GP vaccine**) combines just one of several proteins from the Ebola virus, which cannot cause Ebola disease, with a weakened form of a common respiratory (cold) virus.

- **The vaccine does not have the whole Ebolavirus disease in it, only a small part of it.**
- **The vaccine cannot give people Ebola.**

Human parainfluenza virus type 3 (HPIV3) is a mild human virus. It causes colds but in adults with normal immune systems it does not become serious or spread beyond the respiratory tract. Vaccine scientists attached a single protein taken from the Ebola virus to the HPIV3 virus to make the vaccine.

Prior Experience with a Similar Vaccine in Humans - HPIV3/EbovZ Glycoprotein Vaccine in Humans
A vaccine similar to the one being studied in this clinical trial, The HPIV3/EbovZ glycoprotein (GP) vaccine, was designed with an Ebola virus protein, the GP inserted into the whole HPIV3 virus. In 2015, 30 volunteers received one or two doses of HPIV3/EbovZ GP as a nasal spray. Overall, the vaccine was well tolerated, and volunteers did not experience many symptoms from it. What was unexpected about this vaccine was that the vaccine virus remained detectable in the nose longer than we had anticipated. Also, a few volunteers had mildly abnormal liver function tests though they did not report any symptoms.

For this clinical vaccine trial, the 2015 HPIV3/EbovZ GP vaccine has been changed to make the immune response to the vaccine better, to reduce shedding of the virus in the nose, and to decrease possible vaccine side effects.

Why You Are Being Asked to Participate
Thirty healthy, adult volunteers are needed for a study to learn more about an investigational vaccine to protect against EVD. The safety and tolerability of the vaccine and the immune response in healthy adults will be the focus of the study. Each volunteer will be given two doses of the investigational vaccine or placebo (salt water). The doses will be given approximately 4 – 8 weeks apart.

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Basic Eligibility Requirements

You are being asked to participate in this study because you agreed to participate in a screening study where you were found to meet the following basic eligibility requirements. If these statements no longer apply, please advise the study team right away:

- You are 18–50 years of age.
- If you are female, 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:
  - menopause
  - you have had surgery to remove your uterus and/or ovaries or tie or permanently block your tubes (tubal ligation or Essure), or
  - You do not have sex with men, or
  - You are consistently using a pregnancy prevention method per label instructions to achieve maximum protection against pregnancy initiated at least one month prior to enrollment and throughout the duration of the study. Acceptable methods of pregnancy prevention are:
    - Condoms, male or female, with spermicide every time you have sex with a male partner
    - Diaphragm with spermicide every time you have sex with a male partner
    - Intrauterine device – Mirena or Copper-T
    - Birth control pills
    - Birth control patch (Ortho Evra)
    - Birth control implant, (Nexplanon),
    - Birth control shot (Depo-Provera),
- The medical history you provided and your blood and urine tests indicate that you are in good health.
- You are available for 12 months.
  - This includes two admissions lasting AT LEAST 11 days in our inpatient isolation unit on the campus of Bayview Medical Center.
- 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 U.S. 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 do not live or have close contact with young infants, the elderly, or anyone with a weakened immune system (such as someone with HIV/AIDS or cancer, or who has had a transplant).
- You do not have history of liver disease.

In addition, now that you have met basic eligibility by participating in a general screening study, we have asked you to participate in the screening and consent visit for the **Phase 1 Evaluation of a Live-Attenuated Human Parainfluenza Virus Type 3 Vectored Vaccine Candidate Expressing Ebolavirus Zaire Glycoprotein GP as the Sole Envelope Glycoprotein.** Today, we are asking you to:

- Read this consent for participation in the vaccine trial carefully and thoroughly

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- Show that you understand this research study by completing a comprehension assessment, receiving a score of 70% or better, and understanding all the questions answered incorrectly
- Sign this document, indicating your consent to participate in this study
- Acknowledge that your questions about the study have been answered to your satisfaction and that your consent to participate in the study is freely given
- Complete a physical exam
- If not already done during a prior screening visit, provide blood samples for laboratory tests, including:
    - HIV test: State law requires that the results of HIV-positive tests be reported to a local health agency.
    - Hepatitis B and 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.
- Accept pregnancy prevention counseling if you are a female
- Participate in a review of inclusion/exclusion criteria
- Read and agree to comply with the **Inpatient Unit Rules**, **Alternate Agreement**, and **Handwashing Best Practice**

Key Study Procedures

We plan to enroll 2 groups, or cohorts, of 15 volunteers each who are willing to receive 2 doses of the investigational vaccine. In each cohort, 10 volunteers will receive the investigational vaccine and 5 will receive a placebo, or fake vaccine, made of salt water. Volunteers will not be told whether they received vaccine or placebo until the end of the study.

In total, 30 volunteers will be enrolled in the study divided between the 2 groups. 20 will receive the vaccine and 10 will receive the placebo. The first group is going to receive a lower dose of vaccine two times and the second group will receive 2 doses of the higher dose. The sample size for this study was chosen based on similar studies.

The 2 doses of vaccine (or placebo) will be given approximately 4 – 8 weeks apart. The HPIV3/ΔHNF/EbovZ GP vaccine will be administered as a nose spray. Because this is an investigational vaccine and a live virus vaccine, it will be given in an inpatient isolation unit.

The total duration of study participation is 360 days from the first dose of the investigational vaccine, and includes 2 inpatient admissions and 8 outpatient follow-up visits.
The CIR inpatient isolation unit is located on the Hopkins Bayview Medical Campus in the 301 Building. The isolation unit is a smoke-free, dorm-like setting where you will live, sleep, and eat with other volunteers. It is well equipped and comfortable.

- Visitors are not allowed.
- Men and women will be enrolled at the same time, but will sleep in different bedrooms.
- If you accept the vaccine and are enrolled in the study you must stay on the unit 24 hours/day until the study doctor says it is safe for you to be discharged.

Each time that you are vaccinated, we will ask you to stay on the isolation unit for at least 7 days after receiving the vaccine. You will be on the unit for 1 or 2 days before you get vaccinated, the day of

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vaccination, and 7 or more days after vaccination. You will need to stay on the unit until the level of the investigational vaccine virus in your nasal wash is very low or gone so that there is low or no risk of spreading the vaccine virus to your family, friends or community.

Each day you are on the unit, we will

- check your pulse, breathing rate, blood pressure, and temperature (vital signs) in the morning and evening
- conduct a physical exam and

perform a nasal wash to collect a nasal secretion sample. To do a nasal wash, the study staff will drip about 2 teaspoons of sterile solution into each nostril and ask you to let the solution dribble out of your nose and into a sterile cup. The solution does not burn and it will not hurt you if you swallow some. This procedure seems odd at first, but the study nurses will guide you through it step by step.

In addition, you will have your blood drawn up to 5 times each admission. Here is a detailed schedule of what you will be asked to do each day on the unit if you agree to be part of this study. The schedule is the same for dose one and dose two:

<u>Day -2 (2 days before study vaccination)</u>

- You will be admitted to the isolation unit.
- Research staff will review your health status and medications.
- Research staff will obtain a blood sample (up to 6 tablespoons) to test for germ fighters and for a complete blood count, PT, PTT and blood chemistry tests.
- If you are female, we will draw blood for a pregnancy test.
- We will obtain a nasal secretion sample (Nasal wash)
- You will have a physical exam
- We will obtain vital signs

<u>Day -1 (1 day before study vaccination)</u>

- Research staff may obtain a blood sample (if not done on Day -2).
- We will obtain a nasal secretion sample (Nasal wash)
- You will have a physical exam
- We will obtain vital signs

<u>Day 0 (Vaccination)</u>

- If you are female, you will have a urine pregnancy test.
- Your vital signs will be obtained.
- You will have a physical.
- A study doctor will give you the HPIV3/ΔHNF/EbovZ GP study vaccine or placebo as a nasal spray in each nostril.
- The medical study staff will observe you for the first 30 minutes after vaccination.

<u>Days 1–6</u>

- You will have 2 blood draws (about 2 teaspoons) for a complete blood count and blood chemistry, including liver function.
- We will obtain a nasal secretion sample (Nasal wash)

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- You will have a physical exam
- We will obtain vital signs

Days 7 until discharge

- You will be discharged from the unit on Day 8 if your nasal wash sample is negative or below the target level for vaccine virus on Days 6 and 7.
- If you are not being discharged, you will continue to have a daily nasal wash, and physical exam
- vital signs will be taken twice a day until discharge criteria are met.
- Research staff will obtain a blood sample (up to 6 tablespoons) to test for germ fighters, your complete blood count, and blood chemistry tests.

If you become ill while in the unit, we will give you medication and supportive care to relieve your symptoms and reduce discomfort. We will continue to monitor your nasal washes, blood count, and chemistry until we are sure that you are not experiencing serious side effects and cannot transmit the vaccine virus to others. You will not be discharged until the Principal Investigator (PI) or designee determines that it is safe for you to leave the unit.

Day 14 (± 2 days) after study vaccination

- You will return to the CIR for a brief outpatient visit.
- Research staff will ask you questions about your health since discharge from the unit.
- You will have a physical examination.
- Your vital signs will be obtained.
- Research staff will obtain a blood sample (up to 6 tablespoons) and a nasal wash to test for germ-fighters and to do a complete blood count.

Second Dose of Live-Attenuated HPIV3/ΔHNF/EbovZ GP Vaccine or Placebo

If you tolerate the first dose well, are comfortable with the study procedures, and do not have any medical problems, we will ask you to take the second dose of study vaccine or placebo approximately 4 to 8 weeks after the first dose. You will receive the same product that you did for the first dose. The second dose requires another 11-day stay in the unit. Your second inpatient stay will follow the same routines and procedures as the first admission and you will receive the second dose of live-attenuated **HPIV3/ΔHNF/EbovZ GP vaccine or placebo** on the second or third inpatient day.

If You Do Not Receive the Planned Second Dose of the Study Vaccine:

- We will ask you to come back about 1 month (Day 28 ± 3 days) after the first vaccination for a blood sample (up to 6 tablespoons) and nasal wash.
- Research staff will ask you about your health since the last visit.
- You will have a physical examination.
- Your vital signs will be obtained.
- We will ask you to come back for several visits to follow your immune responses and for safety. These visits will last for approximately 12 months after vaccination and be on a schedule similar to the outpatient visits of those who receive 2 doses as listed below.

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Outpatient Follow-up

When you are discharged from the isolation unit at the end of your second inpatient admission, we will ask you to complete 7 more outpatient visits so that we can continue to monitor your health and your immune response to the vaccine. **For your safety and for research purposes, it is very important that you complete all of your outpatient follow-up visits on time. We will want to see you in the clinic on the following schedule:**

Day 42 (14 days after 2nd dose ± 3 days)	Day 112 (± 7 days)	Day 360 (± 30 days)
Day 56 (28 days after 2nd dose ± 5 days)	Day 180 (± 14 days)	
Day 84 (56 days after 2nd dose ± 5 days)	Day 270 (± 14 days)	

Your outpatient follow-up visits will be brief and will include the following procedures:

- Research staff will ask you questions about your health, obtain vital signs and a blood sample (up to 6 tablespoons), and do a nasal wash.
- You may have a physical exam, and if you are female, a pregnancy test.

Risks/Discomforts

In this study, there are risks related to the investigational drug and risks related to study procedures.

Risks Related to the Investigational Vaccine

This is an experimental vaccine. It has never been administered to humans. We can tell you what we think the risks will be based on research in animals and human trials of experimental HPIV3 vaccines and other types of vaccines incorporating the Ebola GP.

The side effects of this study vaccine in humans are unknown beyond what we learned in the 2015 trial of the HPIV3/EbovZ GP vaccine in humans described earlier. This vaccine was found to be well tolerated in nonhuman primates (monkeys). None of the animals receiving the investigational vaccine showed any signs of illness following vaccination. In a prior study of the live HPIV3 virus vector in humans, 1 of the 28 volunteers who received the virus developed HPIV3 illness. That person had a runny nose for 2 days. In the CIR 2015 trial of the HPIV3/EbovZ GP vaccine, none of the volunteers developed significant cold-like symptoms. There were some headaches reported. Symptoms of HPIV3 illness can include:

- Fever
- Chills
- Body aches
- Runny nose
- Sore throat
- Cough
- Nasal congestion
- Ear ache
- Headache
- Fatigue

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- Loss of appetite
- Abnormal blood test results

Less common, but potential side effects include:

- Wheezing
- Pneumonia
- Vomiting
- Diarrhea
- Abdominal pain

Findings from the 2015 study:

- Longer than anticipated vaccine virus detection in nasal secretions
- Temporary liver function test abnormalities

It is possible that the HPIV3/ΔHNF/EbovZ GP vaccine could cause a more serious illness, although this was not seen in animal and human studies. In monkey studies with this vaccine, none of the animals got sick. Vaccines using other viruses that have the same Ebola virus protein attached have also been well tolerated in human volunteers. Most of the side effects were mild or moderate. Prior experience with the HPIV3-vectored Ebola vaccine in humans resulted in unanticipated blood test abnormalities in 5 out of 30 vaccine recipients that required additional testing to confirm a return to normal. We believe that this investigational vaccine is less likely to cause shedding than the one in 2015.

Transmission of vaccine virus – if you are still shedding low levels of vaccine virus on discharge, there is a small chance of transmitting the virus to others. This may be dangerous for the very young and for those whose immune system is not normal. You should wash your hands frequently and stay away from very young children, old people, and anyone with a weakened immune system like those with HIV, cancer or history of organ transplant until your nasal wash is negative. This will minimize the risk of transmitting the vaccine virus to family, friends or community.

Allergic reactions such as 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. If you have such a reaction, 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.

Pregnancy and Breastfeeding

The effects of the vaccine on the unborn fetus and breastfeeding infant are not known. Women who are pregnant or breastfeeding will not be eligible to participate in the study. All women who can become pregnant must agree to consistent use of 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

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must be negative before the staff will 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 scheduled study visits or ask you to agree to let us keep checking on you until the end of your pregnancy. You will be asked to sign a medical release form so that we can learn about your pregnancy and your baby's health at birth.

Smokers
No smoking or vaping is allowed on the inpatient unit, so we will ask you to refrain from smoking or vaping as long as you remain on the unit. If you are addicted to nicotine, you may experience symptoms of withdraw. Nicotine patches will be available, and the study doctor will prescribe them for you at your request.

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.
- **Nasal washes** – can cause mild discomfort and, very rarely, a nosebleed. This is like getting salt water in your nose when swimming in the ocean.
- **Isolation** – you may feel bored or anxious about not being able to leave the unit or being separated from family, friends, and the community while you are in the unit. You may need to stay in the inpatient unit longer than you anticipated. The unit will be staffed 24 hours a day, 7 days a week with medical and security staff. There will be planned activities you can choose to participate in or not. There are big screen TVs throughout the unit, games, a kitchen, and a dining area. There are lots of windows with expansive views of Baltimore city.

Do Not Participate in other Studies during This Study
Because this is an experimental vaccine, we do not know what will happen if you take another experimental drug or vaccine at the same time. You significantly increase your risk of illness and injury 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, or steroids or other medication outside the study, whether they are prescribed by a doctor or obtained over the counter. Other vaccines, medications, or treatments might interfere with the germ-fighting ability you develop in response to the study vaccine.

If You Become Ill
We ask that you notify the study staff if you become ill at any time while you are a study volunteer, even if you do not think it is related to the study drug. A study doctor will be available by phone or pager at all times during the study. A study nurse is also available by phone at all times if you have any questions. The study doctor, Dr. Kawsar Talaat, can be reached at 410-502-9627 or 410-336-9164 (24 hours), and the study nurse, Rachel Adkinson, can be reached at 410-550-2725 (24 hours).

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New Findings
We will let you know if we learn anything new about the investigational vaccine that suggests new or increased risks of study participation or leads to changes in our research plan. You may be asked to repeat the informed consent process to ensure you are aware of any changes affecting your participation in the study and confirm that you agree to them.

Benefits
You are a healthy individual and the investigational vaccine does not offer any cure for a pre-existing health condition that you have reported. Therefore, you will not receive any direct health benefits from participating in this study. We do not know if this investigational vaccine will prevent EVD, and you should not assume that you are in any way protected from EVD as a result of receiving this vaccine. 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 admitted to the inpatient isolation unit. You will be paid $180.00 for each day you spend in the unit and $80.00 for each outpatient visit you complete. You will only be paid for the visits you complete. You will be paid a $320.00 bonus for 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.

You will be asked to spend AT LEAST 20 inpatient nights in the unit divided over 2 admissions and complete 8 outpatient follow-up visits. If it takes extra time on the unit to satisfy discharge criteria, you will continue to be paid $180.00 per day. If you are required to complete additional outpatient visits, you will be paid $80.00 per 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 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 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 volunteer:

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

Information describing the study will be posted on a clinical trials registration website. This website can be accessed at: https://clinicaltrials.gov/ Information from this study will be given to the sponsor. The

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sponsor is the organization responsible for financing and overseeing this study. The sponsor of this study is the National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID), Office of Clinical Research Policy and Regulatory Operations (OCRPRO). "Sponsor" includes any persons or companies that are contracted by the sponsor to have access to the research information during and after the study. Information about side effects of HPIV3/ΔHNF/EbovZ GP will also be given to the US Food and Drug Administration (FDA). It may be given to governmental agencies in other countries where the study vaccine may be considered for approval. Medical records which identify you, including photographs, and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by the sponsor, and may be looked at and/or copied for research or regulatory purposes by:

- The FDA
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies to whom certain diseases must be reported
- Governmental agencies in other countries
- Johns Hopkins University
- The Johns Hopkins University Bloomberg School of Public Health

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

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
The biological specimens you give us during this study are important to science. Any unused blood or nasal wash specimens will be stored once this study is completed. 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. 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 and nasal wash samples may be used for future research to learn more about HPIV3 and Ebola vaccines, as well as immune response to vaccines. Samples may be stored at the CIR and the LID, NIAID, NIH. These samples will be used only for research. They will not be sold or used to make products for sale. There will not be any genetic tests done on your blood samples.

Your 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

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illnesses caused by HPIV3 and Ebola. Results from future research using your samples may be presented in publications and meetings, but you will not be identified as a study volunteer.

Cost of Participating 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 for nasal wash specimens so we can see if you are shedding vaccine virus.
The study doctor may ask you to stay until you no longer shed high levels of virus to protect people in the community and/or may ask you to return to the 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 not to participate in the study will not put at risk any present or future employment 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 study staff or the study doctor feels that staying in the study is harmful to your health
- You do not follow instructions from the study 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 with 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:

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- The Johns Hopkins University Bloomberg School of Public Health
- Audit and compliance officers and legal counsel
- The Office for Human Research Protections (the government agency that makes sure that we are conducting the research as planned)
- The U.S. Food and Drug Administration (FDA) and similar regulatory agencies
- The sponsor (National Institute of Allergy and Infectious Diseases [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 running 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 he or she is concerned about any of the safety information.

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 needs resulting from your participation in this research study. This short-term medical care will be paid through our contract with NIH. Short-term medical care will be given at a facility determined by Johns Hopkins Hospital and NIH.

In general, the Johns Hopkins University (JHU), Johns Hopkins Hospital, NIH, or the federal government will not routinely provide long-term medical care or financial payment for research-related injuries. At

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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. JHU, Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, NIH, and the federal government do not have a program to pay you if you are injured or have other bad results from being in the study. However, you do have the right to seek legal counsel if you believe that your injury justifies such action.

Who Do I Call if I Have Questions or Problems?

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

STUDY-RELATED PHONE NUMBER(S):	Kawsar Talaat, MD (Principal Investigator) 410-502-9627 410-336-9164 (24 hours) Rachel Adkinson, BS (study coordinator) 443-287-8013 410-550-2725

Call or contact the JHSPH IRB Office if you have questions about your rights as a study volunteer. 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:

- You have been informed about this study's purpose, procedures, and possible benefits and risks.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to participate 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

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