IRB APPROVED
AS MODIFIED
Aug 19, 2024

Participant Information Sheet and Informed Consent Form

TITLE: RANDOMIZED, DOUBLE-BLIND, PHASE 2 STUDY TO ASSESS SAFETY AND IMMUNOGENICITY OF A/H5 INACTIVATED MONOVALENT INFLUENZA VACCINES AT DIFFERENT ANTIGEN DOSE LEVELS ADJUVANTED WITH AS03® OR MF59®

PROTOCOL NO.: BP-I-23-001
[redacted] Protocol #20242455

SPONSOR: Biomedical Advanced Research and Development Authority

INVESTIGATOR: [redacted]

STUDY-RELATED PHONE NUMBER(S): [redacted] (24 hours)

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

How long will I be in this research?
We expect that your taking part in this research will last 7 months.

Why is this research being done?
The purpose of this research is to determine if an experimental pandemic flu vaccines H5N8 and H5N1with adjuvant are safe and to know if these vaccines will generate enough antibodies to provide protection against the influenza virus.

What happens to me if I agree to take part in this research?
If you decide to take part in this research study, the general procedures include receiving two doses of the assigned flu vaccine, monitoring and blood draws, and tracking any symptoms in a diary.

Could being in this research hurt me?
The most important risks or discomforts that you may expect from taking part in this research include pain, redness and swelling in the arm where the shot is given, headache, muscle pain, joint pain, fever, feeling tired and shivering. Although the likelihood is minimal, severe allergic reactions, such as anaphylaxis, may occur.

Will being in this research benefit me?
It is not expected that you will personally benefit from this research. However, data from this study may potentially be of benefit others in the event of a bird flu outbreak in people.

What other choices do I have besides taking part in this research?
This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

What else should I know about this research?
Other information that may be important for you to consider so you can decide whether to take part in this research are:

An acceptable method of birth control is required for women of childbearing potential from two months prior to Screening until at least four weeks after the last study vaccination.

There is a possibility that identifiers might be removed from your private information or biospecimens and then used or distributed for future research studies without your additional informed consent.

DETAILED RESEARCH INFORMATION

1.0 Introduction

Influenza (flu) A virus is categorized into subtypes based on two proteins on the surface of the virus: hemagglutinin (H) and neuraminidase (N), for example H1N1, H2N2, H5N1, etc. Some types of flu virus are able to infect both humans and some other animals like birds, pigs, and dairy cows. H5N1 flu virus infections were first detected in humans in 1997 following a poultry outbreak in Hong Kong and in China. Since 2003, this flu virus has spread from Asia to Europe, Africa and North America. Currently, one of the flu viruses that infect birds called H5N1 and its subtypes such as H5N8 have resulted in large US outbreaks in poultry and most recently dairy cows. This virus is different from the current “seasonal” or “regular” flu that typically occurs during the colder months and is spread from person to person. You can get vaccines to protect against the seasonal flu.

Pandemic vaccines can only be made and distributed once the virus causing the pandemic is known. As a result of this, there may be significant delays in producing enough vaccine in the early stages of a pandemic. Therefore, it has been suggested that public health authorities build up stockpiles of closely related vaccines in advance of a possible pandemic to minimize delay in immunizing people. Such a vaccine could then be given in the early stages of a pandemic to healthcare or other workers who will be at highest risk during a flu pandemic to protect them against and to prevent rapid spread of infection.

The vaccines that will be examined in this study are experimental vaccines which have not yet been approved by the US Food and Drug Administration (US FDA). This means that these vaccines are only given to people included in research studies.

This study will test pandemic flu vaccines H5N8 and H5N1. These vaccines are manufactured using the same process used to make the seasonal flu vaccine Fluzone® and Sanofi's pandemic vaccine approved by the US FDA under the name Influenza Virus Vaccine, H5N1. The vaccines in this study contain inactivated flu virus that is prepared in chicken eggs.

The study vaccine has a portion of the H5N8 or H5N1 virus that can stimulate the immune system to respond but cannot cause a flu infection. Each vaccine injection will also have an adjuvant. The adjuvant helps the vaccine work better. Two adjuvants called MF59 and AS03A (a full dose of AS03®) are used in this study. The adjuvants have been tested in multiple vaccines in various clinical research studies over many years and is used in seasonal and pandemic flu vaccines licensed in many countries worldwide.

The main purpose of this research study is to determine if these vaccines with adjuvant are safe and to know if these vaccines will generate enough antibodies to provide protection against the influenza virus.

You are being asked if you would like to take part in this clinical research study because you are 18 years of age or older and are of relatively stable health.

This information sheet is provided to allow you to make an informed decision on whether you would like to take part in the study. Take as much time as you need and discuss this information with who you wish to help you decide. You are free to ask questions at any time. Your participation is voluntary.

If you do not want to take part, you do not need to do anything.

If you do decide to take part, you will have to sign the consent form, but you can still withdraw your consent at any time. You will receive a copy of the signed consent form.

2.0 Study Design

The study is planned to involve up to 20 sites across the United States with approximately 1380 healthy male and female Participants, including approximately 780 Participants 18 through 64 years old and approximately 600 Participants 65 years old or older.

Participants will receive one of the study vaccines at 1 of 3 dose levels. These will be mixed with either AS03A at one of two dose levels or MF59.

15 different combinations of the H5N8 or H5N1 vaccine with AS03A or MF59 will be tested based on age. These combinations of the H5N8 or H5N1 vaccine with adjuvant will be referred to as "study vaccine(s)" throughout the rest of this informed consent form. Each Participant in the study will be assigned to 1 of the combinations and will receive 2 study vaccination injections separated by approximately 21 days. In this study, neither you nor your Study Doctor will know what study vaccine(s) or dose level you are receiving.

The type of study vaccine and dose you receive will be selected at random (by chance, like the flip of a coin) from 1 of the groups shown in the table below. Each group will have 60 or 120

Participants. The study will randomly assign 780 Participants 18 through 64 years old equally to 1 of 13 study vaccine groups (A, B, C, D, E, F, G, H, I, J, K, M, and N), and 600 Participants 65 years old or older who will be randomized equally to 1 of 10 study vaccine groups (B, C, E, F, H, I, K, L, N, and O), as listed in the table Study Vaccine Groups.

Study Vaccine Groups:

Study Vaccine Group	Study Vaccine Type	Age Group(s)	Approximate number of Participants
A	3.75µg H5N8 + full dose AS03A	18-64 years	60
B	7.5µg H5N8 + full dose AS03A	18-64 and 65 years or older	120
C	15µg H5N8 + full dose AS03A	18-64 and 65 years or older	120
D	3.75µg H5N8 + half dose AS03A	18-64 years	60
E	7.5µg H5N8 + half dose AS03A	18-64 and 65 years or older	120
F	15µg H5N8 + half dose AS03A	18-64 and 65 years or older	120
G	3.75µg H5N8 + MF59	18-64 years	60
H	7.5µg H5N8 + MF59	18-64 and 65 years or older	120
I	15µg H5N8 + MF59	18-64 and 65 years or older	120
J	3.75µg H5N1 + full dose AS03A	18-64 years	60
K	7.5µg H5N1 + full dose AS03A	18-64 and 65 years or older	120
L	15µg H5N1 + full dose AS03A	65 years or older	60
M	3.75µg H5N1 + MF59	18-64 years	60
N	7.5µg H5N1 + MF59	18-64 and 65 years or older	120
O	15µg H5N1 + MF59	65 years or older	60

3.0 Study Activities and Time Commitment

Your participation in the study will last approximately seven (7) months and will involve 7 visits to your Study Doctor. These visits are inclusive of a Screening period, a Study Vaccination period and an End of Study (EoS) Visit, as shown in the table below. Unscheduled visits may be performed to monitor your safety. If your participation ends before the End of Study Visit, you will be asked to attend an Early Termination (ET) Visit.

During the trial, you will receive two injections of the study vaccine(s) into a muscle in your upper arm. The injections are separated by 21 days (given on Days 1 and 22). You will be monitored for at least 30 minutes after each vaccination.

At the end of the vaccination period, the Study Doctor will continue to monitor you for approximately 203 days or 7 months for safety reasons, even if your participation ends early and you do not receive the second injection.

Please see the Schedule of Assessments in this document for what will happen at each visit.

The activities described in the Schedule of Assessments will be performed during the study to make sure you are able to participate and that you can continue to participate until the end of the study. These activities will also be used to assess your safety and any side effects after you have received the study vaccine.

IRB APPROVED
AS MODIFIED
Aug 19, 2024

Schedule of Assessments

Study Visit and Day	Screening	Visit 1/ Day 1	Visit 2/ Day 8	Visit 3/ Day 22	Visit 4/ Day 29	Visit 5/ Day 43	Visit 6/ Day 203 (End of Study)	Early Termination Visit	Unscheduled Visit
Informed consent: You will be asked to provide informed consent before any study procedures are performed.	X								
General Information and Medical History: You will be asked to provide general information about yourself, and your exposure to poultry. You may be requested to get medical records from other doctors. You must confirm that you will not participate in any other clinical study during this study.	X								
Inclusion and exclusion criteria: Assessment that you can participate in this study at Screening and reassessment at each visit at which a vaccine dose is to be administered (Day 1, Day 22).	X	X		X					

Study Visit and Day	Screening	Visit 1/ Day 1	Visit 2/ Day 8	Visit 3/ Day 22	Visit 4/ Day 29	Visit 5/ Day 43	Visit 6/ Day 203 (End of Study)	Early Termination Visit	Unscheduled Visit
Prior and concomitant medications: You will be asked to provide your medical history and to describe all medications including prescription medications and non-prescription (over the counter) medications you are currently and may have taken recently in the past.	X	X	X	X	X	X	X	X	X
Vital signs: Measurements of body temperature, pulse rate, respiratory rate and blood pressure. Your height and weight will also be measured at the Screening visit.	X	X		X		X		X	X
Physical examination: You will be given a physical exam, which may include examination of head, neck, thyroid, ears, eyes, nose, throat, chest, lungs, heart, lymph nodes, abdomen, skin, muscles and skeleton, nervous system and other if needed, as per your study doctor's judgement.	X	X	X	X	X	X	X	X	X

Study Visit and Day	Screening	Visit 1/ Day 1	Visit 2/ Day 8	Visit 3/ Day 22	Visit 4/ Day 29	Visit 5/ Day 43	Visit 6/ Day 203 (End of Study)	Early Termination Visit	Unscheduled Visit
Pregnancy test: Females of child-bearing age will be asked to provide a urine sample for testing to confirm that you are not pregnant prior to the first and second vaccination (Screening, Day 1, Day 22). Females who are pregnant or nursing a child may not enter this study. Therefore, if you are a female that could become pregnant, you must confirm that you will practice acceptable birth control during this study. The study doctor will discuss which methods are considered acceptable birth control. In order to participate in this study, you must be willing to use one of the acceptable birth control methods for at least 2 months before Screening and intend to use this through at least 4 weeks after the last study vaccination.	X	X		X					

Study Visit and Day	Screening	Visit 1/ Day 1	Visit 2/ Day 8	Visit 3/ Day 22	Visit 4/ Day 29	Visit 5/ Day 43	Visit 6/ Day 203 (End of Study)	Early Termination Visit	Unscheduled Visit
Blood samples to monitor your safety	X		X		X			X	X
Blood samples to assess your immune response	X			X		X	X		
Blood samples for future research	X			X		X	X		
Randomization to a study vaccine group (Day1) and vaccination (Day 1 and Day 22). You will be monitored for 30 minutes following vaccination.		X		X					
Examination of vaccination site		X	X	X	X			X	X
Assessment of any feelings of discomfort		X	X	X	X	X	X	X	X

Study Visit and Day	Screening	Visit 1/ Day 1	Visit 2/ Day 8	Visit 3/ Day 22	Visit 4/ Day 29	Visit 5/ Day 43	Visit 6/ Day 203 (End of Study)	Early Termination Visit	Unscheduled Visit
Receive, review, return and replace diary cards and accompanying materials: You will be provided diary cards and accompanying materials for documenting all observations and any feelings of discomfort. You are asked to fill in the diary card at the same time each day from day of vaccination through 8 days after each vaccination.		X	X	X	X	X		X	X

Screening Visit

At your first clinic visit, your Study Doctor will check to see if you qualify to take part in the study. This will involve completing some procedures and tests, including:

- Signing informed consent
- Providing urine for a urine pregnancy test (females of childbearing potential only)
- Reviewing your prior and current medications, including all prescription drugs, vaccines, herbal products, vitamins, minerals, and over-the-counter medications
- Undergoing an overall physical examination (including measurement of your height and weight)
- Collecting your demographics such as your sex and age, medical and medication history
- Collecting your vital signs (including oral temperature, pulse rate, respiratory rate, and blood pressure)
- In fasting state, taking some blood via a needle stick in a vein in your arm:
    - Collecting blood samples for safety and to assess immune response
    - Collecting blood samples for future research
- Collecting information regarding human immunodeficiency virus and hepatitis B and C infections.

If you qualify to take part in the study, you will be asked to come back for the further visits and will have some further procedures and tests (including taking blood and urine samples). Please also note that you may be asked to repeat a procedure or test if your Study Doctor feels it is needed to evaluate your condition. If the Study Staff advises that you have increased liver function test results, you should follow-up with your primary care healthcare provider.

Visit 1/Day 1: Study Vaccination

You will have the next study visit at the day of the first vaccination. This visit will involve completing some procedures and tests at the study clinic, including:

- Reviewing your prior and current medications and any feelings of discomfort that you may be experiencing
- Confirming that you can still participate in this study
- Undergoing a physical examination, as needed
- Collecting your vital signs repeatedly (including oral temperature, pulse rate, respiratory rate, and blood pressure)
- Providing urine for a urine pregnancy test (females of childbearing potential only)
- Randomizing to a study group and receiving the study vaccine(s)
- Monitoring for at least 30 minutes after the vaccination for your safety
- Undergoing examination of the vaccination site
- Assessing potential side effects of the study vaccine(s)
- Completing a diary card at home between study visits to capture any symptoms and medications you take from the day of vaccination through Day 43. You will be provided instructions for completing the diaries. Some of the days you will also be asked to measure and record your oral temperature and any injection site swelling or redness. Please complete the diary card at the same time each day to capture observations for the prior 24-hour period.

Visit 2/Day 8: Clinic Visit

This visit will involve completing some procedures and tests at the study clinic, including

- Reviewing your prior and current medications and any feelings of discomfort that you may be experiencing
- Undergoing a physical examination, as needed
- Collecting blood samples for safety assessments via a needle stick in a vein in your arm
- Undergoing examination of the vaccination site
- Undergoing safety assessments
- Collecting and reviewing previous diary card information
- Providing new diary card

Visit 3/Day 22: Clinic Visit

You will have the next study visit on the day of the second vaccination. This visit will involve completing some procedures and tests at the study clinic, including:

- Confirming you can still participate in this study
- Reviewing your prior and current medications and any feelings of discomfort that you may be experiencing
- Undergoing a physical examination, as needed
- Collecting your vital signs repeatedly (including oral temperature, pulse rate, respiratory rate, and blood pressure)
- Providing urine for a urine pregnancy test (females of childbearing potential only)
- Taking some blood via a needle stick in a vein in your arm:
    - Collecting blood sample to assess immune response to the study vaccine(s)
    - Collecting blood samples for future research
- Receiving the study vaccine
- Monitoring for at least 30 minutes after the vaccination for your safety
- Undergoing examination of the vaccination site
- Assessing potential side effects of the study vaccine(s)
- Collecting and reviewing previous diary card information
- Providing new diary card

Visit 4/Day 29: Clinic Visit

This visit will involve completing some procedures and tests at the study clinic, including:

- Reviewing your prior and current medications and any feelings of discomfort that you may be experiencing
- Undergoing a physical examination, as needed
- Collecting blood for safety assessments via a needle stick in a vein in your arm
- Undergoing examination of the vaccination site
- Undergoing safety assessments
- Collecting and reviewing previous diary card information
- Providing new diary card

Visit 5/Day 43: Clinic Visit

This visit will involve completing some procedures and tests at the study clinic, including:

- Reviewing your prior and current medications and any feelings of discomfort that you may be experiencing
- Undergoing a physical examination, as needed

- Collecting your vital signs (including oral temperature, pulse rate, respiratory rate, and blood pressure)
- Taking some blood via a needle stick in a vein in your arm:
    - Collecting blood sample to assess immune response to the study vaccine(s)
    - Collecting blood samples for future research
- Undergoing safety assessments
- Collecting and reviewing previous diary card information

Visit 6/Day 203: End of Study Visit

This visit will involve completing some procedures and tests at the study clinic, including:

- Reviewing your prior and current medications and any feelings of discomfort that you may be experiencing
- Undergoing a physical examination, as needed
- Taking some blood via a needle stick in a vein in your arm:
    - Blood sample to assess immune response to the study vaccine(s)
    - Blood samples for future research
- Undergoing examination of the vaccination site, as needed

Early Termination Visit / Unscheduled Visits

This visit will be conducted for reasons such as an abnormal laboratory result or as needed, and involves completing some procedures and tests at the study clinic, including:

- Reviewing your prior and current medications and any feelings of discomfort that you may be experiencing
- Undergoing a physical examination, as needed
- Collecting your vital signs (including oral temperature, pulse rate, respiratory rate, and blood pressure)
- Collecting blood for safety assessments via a needle stick in a vein in your arm
- Undergoing examination of the vaccination site
- Undergoing safety assessments
- Collecting and reviewing previous diary card information
- Providing new diary card, if needed (Unscheduled visit only)

Samples

In total 13 tablespoons (or 196 milliliters) of blood will be taken during the study for safety monitoring, assessing your body´s immune response to the study vaccine(s) and for future research purposes.

There is a possibility to draw additional blood samples at an Early Termination or Unscheduled Visit to monitor your safety. Your blood samples will be tested by ICON Laboratories Inc., USA. Your blood samples for immune response assessment will be tested by Battelle Memorial Institute, USA.

If you are a woman capable of having children, you will be required to have three urine pregnancy tests to make sure you are not pregnant during the study and additional pregnancy tests if pregnancy is suspected.

Future Research

Blood samples will be taken for future research as a mandatory part of the study. Future research means that your blood samples taken specifically for future research during the study will be stored by the Sponsor and tested in the future. Blood serum will be stored indefinitely.

By signing this informed consent form, you are giving permission to store any blood samples from research laboratories for an indefinite period of time for future investigations, such as testing for immune response to different strains or subtypes of flu viruses. The future research may be similar to this study or may be completely different. It may be conducted by BARDA or by other researchers.

The future use of your samples may result in new discoveries that are important to the understanding of the vaccine(s) or disease. However, the results of these additional research studies will not be shared with you.

The blood samples that are stored will not be used for genetic testing.

4.0 Risks and Possible Side Effects

Some procedures that will be done during the study may carry some risks, these are given below, and your Study Doctor can provide more information to you.

Possible Vaccine Side Effects

We do not know all the possible side effects of the study vaccine(s). Like all medicines, the study vaccine(s) can cause side effects, although not everybody gets them. Most side effects are mild to moderate. However, some people may experience serious side effects and may require treatment.

Vaccines against different pandemic influenza viruses have been made in the same way as the H5N8 and H5N1 vaccines used in this study.

Based on what we know so far from studies with these vaccines, the most likely side effects you may have from the study vaccines are:

- Pain, redness and swelling in the arm where the shot is given
- Headache
- Muscle pain
- Joint pain
- Fever
- Feeling tired
- Shivering

Less common side effects you may have are:

- Bruising, hardness, warmth or itching in the arm where the shot is given
- Swollen or painful glands (lymph nodes) near where the shot is given
- Sweating
- Nausea
- Diarrhea

As for all vaccines, severe allergic reactions, such as anaphylaxis, may occur. Although the likelihood is minimal, allergy to any component of the influenza vaccine, such as residual egg protein, may trigger a severe reaction that could be life-threatening if not promptly treated. Medications are available at the clinic in order to treat the possible allergic reactions. Guillain-Barré syndrome (numbness, weakness, problems with balance and coordination) has been associated with some influenza vaccines, although the mechanism of this adverse event is unclear.

One of the study vaccines used in this study has small amounts of a mercury-containing preservative called thimerosal. Thimerosal can cause rare allergic reactions in some individuals.

Adjuvant Related Risks

Rarely, adults and children who have received vaccines with adjuvants have developed illnesses called autoimmune diseases. Autoimmune diseases have also occurred in people who have not been vaccinated. Autoimmune diseases develop when immune cells that normally protect you from illness, attack your organs instead. Autoimmune diseases can be serious and can also be lifelong. They can involve for example your liver, kidneys, skin, joints, eyes, brain, as well as other parts of the body. Since no one knows for sure whether this adjuvant causes autoimmune diseases, the manufacturers (GSK, CSL Seqirus) monitor the safety of adjuvants continuously.

There are reports of an illness called narcolepsy (excessive daytime sleepiness) in people who received a different influenza virus vaccine called Pandemrix, which contained the adjuvant AS03®, during the H1N1 (swine flu) pandemic in 2009. People with narcolepsy fall asleep suddenly during the day or may feel sleepy during the day and may have muscle weakness. There is no known cure for narcolepsy and the condition can last for life. Some studies in Europe have reported an increased risk of developing narcolepsy in some individuals who were vaccinated with Pandemrix. The vaccines used in this study are against H5N8 and H5N1 bird flu and use AS03A as an adjuvant. Narcolepsy has not been identified as a risk in clinical trials of pandemic flu vaccines which used the AS03® adjuvant. The manufacturer (GSK) continues to carefully monitor any reports of narcolepsy.

Risks Related to Blood Sample Collection

When you give blood, you may feel faint, or have mild pain, bruising, irritation, or redness where the blood is taken. In rare cases, you may get an infection.

Reproductive Risks

The effect of the study vaccines used in this study on an unborn child or female and male fertility is not known. If you think you might be pregnant during the study, you must contact the Study Doctor immediately. If you become pregnant during the course of the study, you will not receive any further study vaccine, and the study staff will contact you for information including regarding the health, the date of conception, the course of the pregnancy, the medical treatments you may receive and health of your baby following birth. You will be encouraged to continue in the study for safety follow-up.

Other Risks

Any visit to a clinic or a hospital has the risk of potential exposure to you which may result in a clinic and/or hospital-acquired infection. The site will follow local requirements to ensure that infection control measures are in place to minimize this risk.

Also, there may be other risks and side effects that are not yet known.

All risks and side effects will be monitored throughout the study. For this reason, please contact the study doctor immediately if you think you are having side effects or experiencing a change in your health condition.

5.0 Potential Benefits

There are no expected direct medical benefits to you as a result of taking part in this study. However, data from this study may help to determine whether the vaccine(s) or combination of vaccines that are being studied are effective and safe and therefore potentially be of benefit in the event of a bird flu outbreak in people.

6.0 Responsibilities

As a Participant in this study, you have certain responsibilities. You are agreeing to:

- Complete all required visits at the study center and be available by telephone
- Receive two doses of the assigned study vaccine
- Tell the Study Doctor your full medical history
- Tell the Study Doctor what medications including prescription, or over the counter, or vitamins, supplements, and herbal remedies
- Tell the Study Doctor and study staff about any changes in your health, including any side effects and changes or new medical problems you experience during the study
- Tell the Study Doctor if you become pregnant
- Complete the diary cards
- Provide blood samples to measure the effect of receiving the study vaccine;
- Provide urine samples to confirm that you are not pregnant (only applicable for females of child-bearing age)
- Follow the Study Doctor's and study staff's directions and instructions
- Allow the Study Doctor to perform some tests to assess your health for participation in the research study

7.0 Compensation

As a healthy volunteer, you will receive a $[redacted].00 stipend payment per completed visit and a $[redacted].00 stipend payment per completed unscheduled visit for taking part in the study, including reimbursement for reasonable expenses for travel costs for attending the study visits. It is not expected to cost you to participate in the study. The study vaccine(s) will be provided to you free of charge and you will not be charged for any procedure performed for this study.

The Sponsor has a contract with the Study Doctor/study center who will receive payment for taking part in this study.

8.0 Insurance

The Sponsor has taken out an insurance policy for the study that complies with current local law. If you are injured or your health is affected, the insurance taken out by the Sponsor will cover all reasonable and necessary medical costs to treat the injury or illness, if the injury or health issue was directly caused by the study vaccine(s) or correctly performed study procedures. Please refer to the contact details, listed in this document, for information at your study site. Taking part in this study may affect any personal insurance policies you have, such as health insurance, and you should contact your insurer to check if this is the case. Please note,

that if you are in a Medicare or Medicaid plan, you are advised to tell your plan before study participation.

The H5N8 and H5N1 study vaccines, the adjuvants AS03A and MF59, and the efforts for this clinical trial are covered under the Public Readiness and Emergency Preparedness Act (PREP Act) and the Declaration issued by the Secretary of the US Department of Health and Human Services (HHS) under that Act.

If you suffer a serious physical injury or death from the administration or use of the study vaccine(s), you or your legal representative or may request benefits from the Countermeasures Injury Compensation Program (CICP). Compensation may be available for reasonable and necessary medical benefits, lost wages and/or death benefits to eligible individuals for certain injuries in accordance with regulations published by the Secretary of HHS (found at 42 CFR part 110). The CICP only covers expenses or provides benefits that other third-party payers (such as health insurance, the Department of Veterans Affairs, or Workers' Compensation programs) do not have an obligation to pay.

9.0 Voluntary Participation/Withdrawal

You can choose whether you want to take part in the study, and you can change your mind at any time. If you decide not to take part, or stop taking part after the study has started, this will not affect your future treatment and care. If you want to withdraw from the study you should contact your Study Doctor or study staff.

Your Study Doctor may also decide that you should no longer take part in the study if it is in your best interests or if you do not follow the instructions you receive for taking part in the study. The Sponsor, Ethics Committee or Regulatory Authority may also decide to stop the study at any time for any reason.

If you decide to no longer take part in the study, or your Study Doctor decides you should no longer take part you will be asked to attend an Early Termination visit to ensure it is safe for you to no longer be monitored by the Study Doctor. You can discuss any follow-up measures with your Study Doctor if you stop participating in the study. You will not take part in the study after withdrawal.

Please note that ending your study vaccination(s) is not the same as ending participation in the study. Knowing your health status is important for the study. It will help us to learn more about the potential effects of the study drug. If you withdraw your consent to continue to take the study vaccine(s), you are asked to continue in the study for safety follow-up and complete the study visits and safety assessments as available.

If there are significant new findings available on the study vaccine(s) during the study which might make you change your mind about taking part in the study, you will be informed of these significant new findings without delay.

If you wish to withdraw your consent for Future Research with blood samples, you may withdraw your consent by contacting the Study Doctor. After your participation in the study has ended, you can contact BARDA (202-260-1200 or 200 Independence Ave., Washington, DC 20201). Samples will be destroyed, but any data that have already been collected from analysis of serum will remain a part of the research database.

IRB APPROVED
AS MODIFIED
Aug 19, 2024

10.0 Who to Contact with Questions or Report a Possible Study Related Injury or Reaction

If you have any questions about the study or your rights, at any time, or think you have experienced an injury or reaction to the study vaccine(s), you should contact your Study Doctor through the contact details listed in this consent. In the event of injury or reaction, the Study Doctor will treat you or refer you for treatment.

The study has been approved by [redacted] IRB (Institutional Review Board), which is an independent committee established to help protect the rights of research Participants. If you have any questions about your rights as a research Participant and/or questions, concerns or complaints regarding this research study, you should contact [redacted] IRB at [redacted] or [redacted].

11.0 Confidentiality and Data Protection

The words in **bold text** are in a glossary of terms found in this document for reference.

11.1 What **personal data** is being processed?

Your **personal data**, including your demographic information (race, ethnicity, sex at birth, age), medical history and data from laboratory samples will be collected during the study. Only **personal data** needed to run the study properly and safely will be collected.

11.2 Who will be able to see your **personal data** and how will it be protected?

The Sponsor and those working on the study will only be given as much information from your medical records as is needed for the correct running of the study.

Coded Data

Your personal data is safeguarded by giving it a **Participant (subject) ID number** and is called **coded data**. Your **coded data** will be accessed by people who are working for or on behalf of the Sponsor and its **affiliates** in connection with the study and external people such as the **IRB** and **regulatory authorities** which reviewed and approved the study.

They will not be given your name, where you live or anything that could identify you. Your medical data and any samples will be labelled with your **Participant ID number** only. Your **coded data** will be stored and analyzed under the **Participant ID number**. In the case of emergency, the study site can trace the information back to you.

The Sponsor is responsible for all your **coded data** collected during the study. They are responsible for making sure all those working on the study comply with the data protection requirements for the collection, use and processing of **personal data** collected for this study.

Non-coded data

The **non-coded data** will be recorded by the Study Doctor in your medical records and medical chart and remain the responsibility of the Study Doctor.

To make sure the study is run properly and ensure data is recorded correctly it may be necessary for the following people to look at your **non-coded data**.

- The Principal Investigator, who is the person who directs the trial and who knows the Participant's identity at all times. You can find the contact details of the Principal Investigator listed in this document.

- The Principal Investigator's Team, which are the health professionals who collaborate with the Principal Investigator in the management of the clinical research and also know the Participant's identity.
- The Monitor (contracted from a Clinical Research Organization, CRO called ICON plc, USA), who supervises that the clinical research is being carried out correctly and ensures that the information is obtained appropriately at the research site.
- Contract Research Organizations Rho, USA, and ICON plc, USA who are responsible for allocation of study drug and supervises the electronic study data and the Participant diaries captured during the study
- The Auditor, who is the entity that corroborates that all actions carried out in a clinical investigation are carried out correctly, and must access your identity to carry out these checks.
- Specific authorized employees of the Sponsor and persons acting on the Sponsor's behalf who are working on the study
- Representatives of any **Regulatory Authority, the US FDA**
- Representatives of the **IRB** (where applicable)

These people may view your medical records remotely (from a location outside of the study center).

11.3 How long will your coded data be kept for?
The **coded data** will be kept indefinitely. It may be used and shared for similar future research purposes related to the use of the study vaccine(s) but your privacy would continue to be protected as only coded data would be used. Your identity will be kept confidential unless it is provided with your agreement.

11.4 Can you see the **personal data** collected and recorded about you?
To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete. At the conclusion of the research and at your request, you generally will have access to your health information that the study site maintains in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at the study site to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by the study site. If it is necessary for your care, your health information will be provided to you or your physician.

11.5 Where will your **personal data** be sent**?**
The Sponsor or their representative may need to send your **coded data** to other countries. The reason for sending the data is to support data analysis and possible applications for new vaccines. The Sponsor is required to protect your privacy and send any **coded data** in a secure way as required by law. You can ask them to provide more information about this through your Study Doctor.

11.6 Information about your **personal data**
All reasonable measures to protect the confidentiality of your study records and your identity will be taken to the extent permitted by the applicable laws and/or regulations and will not be made publicly available.

This research is covered by a Certificate of Confidentiality (CoC) from BARDA, Administration for Strategic Preparedness and Response, a US Federal Government entity under HHS.

This means that the staff of the study site and their subcontracts cannot share or give to any other person not connected with this research your name, information about you, documents, or samples that may identify you in any action or suit unless you say it is okay.

A CoC protects your private information from all legal proceedings. Your information can't be used as evidence even if there is a court subpoena. All copies of your information are immune from the legal process, and cannot, be admitted as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding unless you say it is okay.

The information about you CAN be shared for other research if it is allowed by Federal regulations. We will let you know beforehand if this is something we will do.

The Certificate DOES NOT stop the reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the US FDA.

You should understand that a CoC does not keep you from voluntarily releasing information about yourself or your involvement in this research. It also does not prevent you from having access to your own information. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide specific consent to allow the researchers to release it. If your health information includes mental health, HIV/AIDs or substance use and treatment, then it might be made available as part of this study. For example, if you are on a medication to treat AIDs or a mental illness, that medication may be included in the health information that will be shared by your health care provider. Or if your health care provider needs to share your diagnoses, this information may be included. By signing this document, you consent to the use and disclosure of this information for the purpose of this study.

HIPAA (Health Insurance Portability and Accountability Act) Regulations or applicable state law requires that you authorize the release of any health information that may reveal your identity.

By signing this form, you authorize the following persons and entities to use or disclose your individually identifiable health information at the request of the individual for the purpose of carrying out the study as described in this form: the Study Doctor, the study staff, the Institution, the Sponsor and authorized Sponsor representatives such as the CRO´s, central laboratories and the courier company for the purpose of carrying out the study as described in this form. This purpose will not include the use or disclosure of your health information for marketing. While the Study Doctor/study site will receive payment for taking part in this study, this payment does not include the sale of your health information. Once your protected health information has been disclosed to a third party, Federal privacy laws may no longer protect it from further disclosure and the third party may share your information with others outside this authorization. Once your protected health information (PHI) has been disclosed, it is possible that the receiver may re-disclose the information and the information is no longer protected.

In order to analyze the data collected during this research study, all of the health information generated or collected about you during the study may be inspected by the study Sponsor or the authorized agents of the Sponsor, the US **FDA**, HHS other government regulatory agencies from other countries, the central Ethics committee [redacted] IRB, as well by representatives of BARDA or their designee the Study Doctor, the study staff, the Institution, and authorized Sponsor representatives. In addition, your health information will be used or disclosed when required by law, and may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions.

The results of this study may be presented at meetings or in publications; however, your identity will not be disclosed in these presentations. By signing the informed consent form, you are authorizing such access to your medical records.

You do not have to sign this authorization, but if you do not, you will not be allowed to participate in the research study. Choosing to refuse will not affect your treatment. You may change your mind and revoke (take back) this Authorization at any time by writing to the Study Doctor. Even if you revoke this Authorization, the Study Doctor, the study staff, the Institution, the Sponsor and authorized Sponsor representatives may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to the study site.

If not revoked this authorization will not have an expiration date. In California or any other state that requires and expiration date, this authorization will expire December 31, 2070.

If you wish to withdraw your consent for future research, please contact the Study Doctor identified above. After your participation in the study has ended, you can contact BARDA (202-260-1200 or 200 Independence Ave., Washington, DC 20201). Blood samples will be destroyed, but any data that have already been collected from analysis of serum will remain a part of the research database.

You understand that if all information that does or can identify you is removed from your health information in compliance with de-identification laws, then the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

11.7 Where will study information be made publicly available?

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.

Glossary of Terms

Affiliate	A person or organization officially attached to the Sponsor, for example the Sponsor offices in other countries
ClinicalTrials.gov	ClinicalTrials.gov is a US database of clinical studies conducted around the world. Information like the purpose of a study, timelines, status, results, etc. can be searched on this website
Coded Data	The Participant is allocated an identification number and all data and samples related to that Participant are held under this number.
Participant (subject) ID number	Identification number allocated to each Participant that is included in the research study.
US FDA	United States Food and Drug Administration – the agency responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs, vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices, cosmetics, animal foods & feed and veterinary products
Institutional Review Board (IRB)	An Institutional Review Board is a type of committee that applies research ethics by reviewing the methods proposed for research to ensure that they are ethical and safe
Non-coded data	Data which may directly identify you including parts of your medical records and charts relevant to the study.
Personal Data	Any information that can directly identify you, such as full name, address, date of birth, health information such as non-coded data or indirectly, such as coded data.
Regulatory Authority	A regulatory authority is a government agency set up to enforce safety and standards and to protect Participants.

IRB APPROVED
AS MODIFIED
Aug 19, 2024

12.0 A/H5 Inactivated Monovalent Influenza Vaccine Study

PREP ACT Information Sheet

Dear Participant,

We know that understanding your rights in a clinical trial can sometimes be overwhelming. That's why we're here to provide you with clear information about the PREP Act (Public Readiness and Emergency Preparedness Act) and how it may relate to you.

What is the PREP Act?
The PREP Act stands for Public Readiness and Emergency Preparedness Act. It is a federal law enacted to provide immunity from liability for certain individuals and entities involved in the production, distribution, and administration of medical countermeasures such as vaccines, medications, and medical devices during public health emergencies.

How Does the PREP Act Protect You?
The PREP Act is designed to ensure that medical countermeasures can be rapidly developed and distributed during emergencies without the fear of legal liability. This protection extends to manufacturers, distributors, healthcare professionals, and certain other individuals and entities involved in the response to public health emergencies.

Filing a Claim under the PREP Act
If you believe you have experienced an injury or adverse reaction as a result of receiving a covered countermeasure under the PREP Act, you may be eligible to file a claim under the Countermeasures Injury Compensation Program (CICP).

Here's how you can file a claim: **855-266-2427** (toll-free) or http://www.hrsa.gov/cicp/

Step 1: Gather Information
Collect any documentation related to the administration of the countermeasure, including medical records, receipts, and any other relevant documents.

Step 2: Complete the Claim Form
Download the claim form from the CICP website or request a copy by calling the CICP office. Fill out the form completely and accurately, providing all requested information.

855-266-2427 (toll-free) or http://www.hrsa.gov/cicp/

Step 3: Submit Your Claim
Submit your completed claim form and supporting documents to the CICP office by mail or electronically, following the instructions provided on the claim form.

Health Resources and Services Administration
Countermeasures Injury Compensation Program
5600 Fishers Lane, 08N146B
Rockville, MD 20857
cicp@hrsa.gov
1-855-266-2427 (1-855-266-CICP)

Step 4: Await Review
Once your claim is received, it will be reviewed by the CICP office to determine eligibility for compensation. This process may take some time, so please be patient.

Step 5: Receive Decision
You will be notified of the decision regarding your claim. If your claim is approved, you may be eligible to receive compensation for eligible expenses related to the injury or adverse reaction.

Important Points to Remember
Keep copies of all documents related to your claim for your records.

Be honest and thorough when completing the claim form.

If you have any questions or need assistance with the claims process, don't hesitate to contact the CICP office for help.

Contact Information
Countermeasures Injury Compensation Program (CICP)

Website: https://www.hrsa.gov/cicp
Phone: 1-855-266-2427
Email: cicp@hrsa.gov

We hope this information helps you understand the PREP Act and the process for filing a claim. If you have any further questions or concerns, please don't hesitate to reach out to us or the CICP office for assistance.

Participant Informed Consent Form

I have received information on the abovementioned study and have had the opportunity to read the information and to ask questions and have received answers.

I voluntarily consent to:

- Participate in the study.
- Follow the instructions provided by my Study Doctor.
- The processing of my personal data, to include but not limited to medical information as notified by this form and derived from the study.
- The transfer of my personal data to countries outside of my own where data protection might differ from the data protection in my country.
- The Sponsor and its representatives, as well as Regulatory Authorities, to compare data reported in the study to those contained in my medical records. I consent to this under the condition that the information obtained is not disclosed.
- Be contacted with a request to participate in future clinical studies of Participants who have been vaccinated against H5N8 or H5N1.
- Storage of blood samples for future research.
- The use and disclosure of my personal health information.

I know that at any time and without giving any reason. I can withdraw my consent by contacting the Study Doctor and stop taking part in the study. This will not affect my future treatment and care.

I will receive a signed copy of this Participant Information Sheet and Informed Consent Form for my records.

IRB APPROVED
AS MODIFIED
Aug 19, 2024

Signatures

Participant	
	Print Name
Signature	Print Date

Study Personnel Performing Consent	
	Print Name
Signature	Print Date

Principal Investigator	
	Print Name
Signature	Print Date