Consent Document Cover Page

Study title: Characterizing Late-season Influenza Vaccine Responses to Compare the 2023 and 2024 Vaccine Formulations

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La Jolla Institute FOR IMMUNOLOGY | Life Without Disease.®

Consent for Research Study

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Summary Information Section

Informed Consent
You are being invited to take part in a research study. Research is done to learn new information. You will not receive any treatment as part of this study. We expect up to 60 people to take part.

It is important that you know the procedures and risks involved in this research. These will be discussed with you and are included in detail later in this form. Review the information carefully and ask the clinical studies team any questions that you have. Take as much time as you need to make your decision. This process is called informed consent.

Voluntary Participation
Taking part in this study is completely voluntary. You may choose not to participate or choose to stop participating at any time. There will be no penalty to you if you decide not to participate.

Purpose
The purpose of this research is to learn more about the immune system response after getting a flu vaccine. We will be trying to answer questions such as: How strong is the immune response post-vaccination? How long does it last? Answering these questions will help us to design better vaccines in the future.

Duration
You will be in the research study for 7-10 months, during which you will visit the Institute 6 times and receive two flu vaccines.

Procedures
This study will include 6 blood draws (1 per visit) using standard blood drawing methods. During your first visit, you will receive the 2023-24 seasonal influenza vaccine. During your fourth visit, you will receive the 2024-25 seasonal influenza vaccine. Both vaccines will administer Fluzone through an intramuscular injection like you would receive from your healthcare provider.

When receiving an intramuscular vaccine, a trained medical professional will ask which upper arm muscle you want to have the vaccine administered in. Next, they will sterilize the upper arm and inject the vaccine. You may be monitored for up to 15 minutes following the vaccination.

Since this vaccine was made for the 2023-24 flu season that officially ends in July, the first vaccine you receive will not replace the updated vaccine for the upcoming 2024-25 flu season. On the other hand, the second vaccine (from your fourth visit) will provide you the best chance of protection for the 2024-25 flu season.

Risks
Occasionally a blood draw can cause some discomfort, bleeding or bruising. Some people can feel light-headed or even faint after a blood draw. Receiving an intramuscular vaccine may result in soreness, redness and swelling where the shot was given. Some individuals also experience fever, muscle aches and headache.

Possible Benefits
You will not personally benefit from taking part in this research but other people may be helped in the future by what is learned.

Costs
There are no costs to you for participating in this study.

Payment
You will receive $25 for each blood donation. If you have traveled to LJI but are unable to participate you may be eligible for $25 in compensation for time and travel. Compensation will be issued to you in the form of a check after the donation or visit. A check may be mailed to you. It can take up to 4 weeks to arrive after blood donation(s) have been completed.

Research Results
You will not be given any research results from this study.

Storage and Future use of Samples and Data
Your sample and the data generated from your sample may be stored for future research or shared with other researchers.

Detailed Information Section

Study Visits and Timeline

There will be 6 study visits. During your first visit, we will explain the study to you and get your informed consent to participate in the study. We will ask you some questions about your health history, and if you meet the eligibility criteria your initial visit may also include a blood donation and vaccination. Your second and third visits will only include a blood donation. Your fourth visit will be much like the first visit, where we will get your additional informed consent to participate in the latter half of the study followed by a blood donation and vaccination. The fifth and sixth visits will only include a blood donation. You may decline to participate or give additional samples at any time.

Procedures

The timeline for your six visits will be:

- May-Jun 2024: Blood donation + vaccination
- Jul 2024 (1 month later): Blood donation
- Sep 2024 (3 months later): Blood donation
- Sep-Nov 2024: Blood donation + vaccination
- Dec 2024 (1 month later): Blood donation
- Feb 2025 (3 months later): Blood donation

While you are in this study, these are the procedures that will be carried out.

Vital Signs
Before the blood donation, a healthcare professional may weigh you and check your height, blood pressure, pulse, and hematocrit levels (amount of red blood cells that you have). These tests help the staff determine whether it is safe for you to donate blood. To check your hematocrit, s/he will use a small lancet (a small instrument with a sharp tip) to prick your finger. If your hematocrit and vital signs are not within the acceptable range (as listed in the inclusion criteria), you may be given the choice to try again in several weeks; otherwise, study participation will end at this point.

Blood Draw
You will be asked to give 20mL (or ~1.5 tablespoon) of blood each visit. We will never exceed 550 mL (~40 tablespoons) in any 8-week period, which has been deemed safe by the Red Cross and the American Association of Blood Banks. The study staff will explain the procedure to you, and what is involved prior to any appointments. If you have ever felt dizzy or fainted as a result of having blood drawn in the past, you should inform the phlebotomist, and s/he will have you will lie down while blood is being drawn.

All blood donations will be collected by standard blood drawing procedures, performed by a qualified healthcare professional (physician, nurse, or phlebotomy technician). Blood donations will be performed at La Jolla Institute (LJI), 9420 Athena Circle.

Intramuscular Inactivated Influenza Vaccine
The intramuscular muscular influenza vaccine is an approved seasonal vaccine that contains pieces of the virus that that causes the flu. This vaccine can be designed to protect against 4 types of influenza: an influenza A (H1N1), influenza A (H3N2), and 2 influenza B viruses. An LJI clinical staff member will begin by explaining the procedure. When receiving an intramuscular vaccine, a trained medical professional will ask which upper arm muscle you want to have the vaccine administered in. Next, they will sterilize the upper arm and inject the vaccine. You may be monitored for up to 15 minutes following the vaccination.

Risks

Taking part in this study involves certain risks. There may also be risks that are not known at this time. If you have any medical issues during this study, call the appropriate number in the "Problems or Questions" section of this form.

Risks associated with the blood draw: Bleeding, bruising, discoloration, and infection around the area where the needle is inserted, and rarely fainting.

To minimize the risks of blood draw: Only certified staff using standard procedures will draw your blood. LJI clinical staff will track how much blood you have given and safe levels will never be exceeded. You may recline during and after blood draws and will be offered juice and/or snacks after blood withdrawals to minimize the risk of feeling bad. You should report any problems to the clinical staff immediately**.**

Risks associated with inactivated intramuscular influenza vaccine: Receiving an intramuscular influenza vaccine may result in soreness, redness, and swelling where the shot was given, fever, muscle aches, and headache are also possible after receiving the vaccine. There is a very small, elevated risk of Guillain- Barré Syndrome (GBS), after the inactivated influenza vaccine. This entails a rapid progressive paralysis. However, most people recover fully. These side effects are all CDC-recognized risks following inactivated influenza vaccination.

To minimize the risks of inactivated intramuscular influenza vaccine: These procedures will only be carried out by trained medical professionals in an appropriate clinical setting following explanation of the procedure and agreement by the participant to proceed.

Risk of loss of confidentiality: Although your privacy and confidentiality will be protected during the course of this study, there is the risk of the possible loss of confidentiality.

To minimize the risks of loss of confidentiality: To protect confidentiality, all specimens are assigned a random ID number that is linked to your identifying information (such as name, contact information, etc.). The ID number linking each blood sample to you will be kept in a locked cabinet that is only accessible to the clinical staff. Samples sent to researchers and collaborators will be labeled with only the coded ID number and no personal identifying information. Your name will never be associated with any particular research project, and any publication of the results of any research project will never identify the name of any donor.

Privacy and Confidentiality

Your personal information will only be used by and shared with the clinical staff. The researchers will never be given your name or other personal information.

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.

Ending Study Early

If you wish, you may stop taking part in the study at any time. The study team may end your participation at any time after your first study visit: some examples of why you may not be asked to continue in the study following your pre-vaccination visit include vaccine dose availability, sufficient cohort enrollment, or because the samples are difficult to analyze or interpret. The research personnel will discuss the reasons if this becomes necessary. If you become pregnant while enrolled in the study you should inform the study team and discontinue donating blood.

Storage and Future use of Samples and Data

Some of your sample and/or the data generated from it may be stored for future research that is not yet planned. In this case you will not be contacted to provide additional consent. There is no scheduled date on which your samples and data will be destroyed. Your samples may be stored for research until they are "used up". Your sample and/or data from this sample may be shared with other researchers at LJI, collaborating institutions or other companies. In this case, the sample or data will be deidentified and will never be associated with your name, address, phone number, or any other information that would identify you. If your sample is used for a project that results in commercial profit you will not receive a share in that profit.

Research-Related Injuries

If you are injured as a direct result of being in this study, and this injury occurs while you are at LJI, LJI clinical staff will provide necessary medical treatment within the scope of their training and resources. If emergency medical assistance is needed for such an

injury, emergency services will be called. If you are having a medical emergency after a study visit, call 911 or go directly to an emergency room. You should let emergency personnel or providers know that you are taking part in this study.

The costs of treatment for a research-related injury may be billed to you or your insurer just like any other medical costs, or covered by LJI depending on a number of factors. La Jolla Institute for Immunology does not normally provide any other form of compensation for injury. For more information about this or research-related injuries and the availability of medical treatments you may contact the LJI Human Subject's Committee at (858)-752-6532.

Problems or Questions

If you have any problems or questions about this study contact the LJI Clinical Studies Core by emailing **donors@lji.org** or calling **(858) 752-6929**. If you have any questions about your rights as a participant in the study, you may call the Institute's Human Subjects Committee **(858) 752-6532**, as noted in the *Experimental Subject's Bill of Rights,* attached to this consent

Genomic Studies

Genomic studies examine differences across the human genome - your set of genes. As part of this study or future studies, genomic research may be performed on your sample. Researchers look at the differences between genes and health conditions or personal characteristics like vision, obesity, and behavioral traits. As part of this study, we will be collecting information about your health and/or your individual genes, but researchers will use this information without knowing who you are (i.e., personal identifying information such as name, phone number, address, will be removed from the data). This research may include whole genome or exome sequencing. This is like taking an inventory of your DNA which contains your genetic information.

Optional - Broad Sharing of Genomic Data

If you agree, genetic data derived from your samples may be entered into outside scientific databases so that it can be broadly shared with other researchers. For example, the National Institutes of Health (NIH, an agency of the federal government) maintains a database called "dbGaP." Databases like this serve as a kind of bank for all kinds of genomic data from studies funded by the NIH and conducted in the US and around the world. The aim of collecting this information in a bank is to allow qualified researchers to look for genetic connections for a range of topics in the future. The information may be used to learn if certain genes are associated with certain traits, diseases and/or treatment effects. Making this information broadly available in this way means that your contribution in this study could be helpful in other areas of scientific research. Your personal information (such as name, phone number, address) will NOT be included in these databases or shared with others. De-identified (data without your personal information) genomic data generated in this study may be deposited in databases that will be publicly accessible via the internet. Researchers with an approved study may access and utilize your de-identified genetic, genomic and/or health information deposited in the database (dB GAP) after approval by the regulatory authority (NIH). Strict safety measures are in place to protect the privacy of your information. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you or your family. The risk of this happening is very small, but may grow in the future. The researchers will always do their best to protect you as they have a duty to protect your privacy and keep your information confidential.

➢If you do not wish your data to be shared in this way, you may still take part in this study and your data will not be submitted to an external database. Please indicate below whether you consent to the sharing of your data in this way.

Consent for Broad Sharing of Genomic Data

____ **I consent** to my genetic, genomic and/or health information being submitted to an external database and broadly shared with other researchers

____ **I do not consent** to my genetic, genomic and/or health information being submitted to an external database and broadly shared with other researchers

You may withdraw consent for research use of genomic data or health information at any time. In this event, data will be withdrawn from any repository, if possible, but data already distributed for research use will not be retrieved.

May we contact you for future research studies?

____ Yes

____ No

By signing this form, you are agreeing that

____ You were given the opportunity to read this form.

____ All of the information in this form was discussed with you by an investigator or other research personnel to your satisfaction.

____ All your questions have been answered to your satisfaction

____You were not pressured and you voluntarily agree to take part in this research.

_____ _____

Print Name of Donor ***Signature of Donor / Date***

_____ _____

Printed Name and Title of Consenting Staff ***Signature of Consenting Staff / Date***

LA JOLLA INSTITUTE FOR IMMUNOLOGY

PLEASE NOTE: As a participant in a research study you are considered an "experimental subject." Your rights as an experimental subject are set forth in California Health & Safety Code §24172 below.

California Health & Safety Code §24172 Experimental subject's bill of rights;

As used in the chapter, "experimental subject's bill of rights," means a list of the rights of a subject in a medical experiment, written in a language in which the subject is fluent. Except as otherwise provided in §24175, this list shall include, but not be limited to the subject's right to:

(a) Be informed of the nature and purpose of the experiment.

(b) Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

(c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

(d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

(e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

(f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

(g) Be given an opportunity to ask any questions concerning the experiment or the procedures involved.

(h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

(i) Be given a copy of the signed and dated written consent form as provided for by §24173 or §24178.

(j) Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

If I have questions about the research study, I can call the contact person listed on the consent form. If I have concerns about the research staff, or need more information about my rights as a subject, I can contact the Human Subjects Committee, which protects volunteers in research studies. I may telephone the committee administrator at 858-752-6532, 9:00 a.m. to 5:00 p.m. weekdays, or I may write to the Human Subjects Committee, La Jolla Institute for Immunology, 9420 Athena Circle. La Jolla, CA 92037.

By signing this document, I agree that I have read and received a copy of this Bill of Rights.

_____ _____

Signature of Subject or Legal Representative Date

_____

Print Name