Clinical Investigation Consent Form
The Rockefeller University Hospital*

IRB Rev 2019

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Title of the research study: An open label study of IgG Fc glycan composition in human immunity

Summary of Key Information:

You are being asked to join a research study, which will take place at The Rockefeller University Hospital. Taking part in a research study is voluntary. This form tells about the research. You should ask questions of the person who is explaining this form to you. You may take an unsigned copy of this form home with you to read again. After you feel that you understand the research, if you want to be part of the study, you will be asked to sign the form. You can always ask more questions and can later change your mind about staying in the study Being in a research study is not part of your routine medical care. You can decide not to be in this study. Alternative to joining this study is that you may choose not to be part of this study.

The purpose of this study is to learn more about how vaccines work in humans.

The study procedures will include four clinic visits, medical and physical examinations, blood draws, provide urine samples, oral swab for HIV testing, complete a medical questionnaire, and receive the influenza vaccine (Fluzone).

It is important for you to know that the main risks associated with a blood draw are generally minor. They are mild pain and some local bruising at the needle site (common), fainting (rare) and infection (extremely rare). For the influenza vaccine, the most common risks are injection site reaction (tenderness, mild pain, swelling, and arm stiffness. The most common systemic risks to the influenza vaccine is mild headache and body aches (myalgia).

The benefit for individuals participating in this study are routine blood work which include screening for Hepatitis B and C, HIV testing and receipt of the influenza vaccine at no cost to you.

Important Information If You Choose to Participate:

Length of time you will be asked to be in this study: If you join the research study, you will take part for about 4 times over 6 weeks. The research study as a whole will last about 10 years.

Number of subjects involved: About 215 individuals will take part in the research study at the Rockefeller University Hospital. About 100 people will be in your group.

Researchers contact number: Taia Wang, MD, PhD, at 212-327-7323.

More detailed information follows below.

I. What this research study is about, and the reason for doing this research.

The reason for doing this research is to learn more about how vaccines work in humans. They are studying how people respond to different vaccines – specifically, they will study the antibodies that your body makes after receiving one of seven different vaccines. Antibodies consist primarily of protein but attached to the protein they also have complex sugar molecules. These are called glycans. Some of the functions of the antibody are very dependent on the kind of glycan it carries. Information about the antibodies you make after vaccination will be used to help understand what factors (your age or the type of vaccine that you received) contribute to the most helpful immune response.

The vaccines being given in this study are all approved by the Food and Drug Administration (FDA) and they will help to protect you against either the flu or bacterial infections. **The vaccine that your group will receive is the flu vaccine (called Fluzone).**

After you receive the vaccine, you will be asked to return to the clinic twice to give a sample of blood so that researchers can monitor your body's immune response. Your participation in the study will end 3 weeks from the day you are vaccinated.

We are asking you to take part in this research study because:

- You are a healthy adult between the ages of 18 and 64;
- Have no current medical conditions;
- Have no allergies to eggs;
- Have not received any vaccine within the last month, and
- Have previously been diagnosed with dengue infection, dengue fever, dengue hemorrhagic fever, chikungunya virus infection, or zika virus infection.

Because pregnancy would likely change the results of this study, we cannot include volunteers who are pregnant at screening or who become pregnant during the 3-week study period.

If you are an employee or student of the Rockefeller University, there will be no negative impact on your employment or student status if you do not wish to participate.

II. What is going to happen in this research study?

Consent Process: Informed consent is a process to help you understand the purpose of the research study, what will happen in the study, possible risks and benefits, and your right to withdraw from the study at any time. All of this information will be explained to you in detail. You should ask any questions you have until you feel that you understand what is asked of you to participate. You may then want to enroll, or you may decide not to join the study. The decision to participate is entirely up to you. Even after the study has started, you may at any time ask more questions, or decide to withdraw from the study.

In this part, we explain the meaning of words that we are going to use to describe this study:

> "**Substances drawn from your body**" refer to **liquids** such as blood or urine. It can also mean tissues such as skin, cells and **DNA**. **Cell**s make up all parts of your body. DNA is inside all the cells of your body and carries your genetic or inherited information. When we draw blood, take tissue, or take other substances from your body, we are taking a "**sample**."

Pre-screening

- Before screening, you will have had the opportunity to review information about the details of the study. You will have the opportunity to talk to the study investigators and ask them questions.

Screening

- Screening will determine whether you are eligible to participate in the study.
- If you agree to be screened, you will sign a copy of the Informed Consent Form (this document) confirming that you have been informed about the study and voluntarily agree to take part. You will be given a copy of the signed consent form.
- You will have your vital signs measured (weight, height, blood pressure, temperature, heart rate, respirations) by a member of the outpatient staff.
- You will be asked questions about your general health and your sexual behavior.
- A medical history and physical exam will be performed.
- You will be given safe-sex and pregnancy avoidance counseling.
- Before having the HIV test, you will be asked to sign a separate informed consent form.
- A rapid HIV test will be performed as an oral swab and you will be told the results.
- Up to 25 ml (approximately 5 teaspoons) of blood will be drawn to test for Hepatitis B, Hepatitis C, pregnancy, chemistries, a complete blood count, and other health conditions, including IgG testing for dengue or chikungunya antibodies if indicated.
- A urine specimen will be collected for analysis.
- Female subjects are advised to use a highly effective form of contraception throughout the study period such as condoms, birth control pills, birth control injections, or intrauterine devices.
- You will be asked to complete a Medical/Family History Questionnaire at this visit.

Study Participation

- If you are found eligible through the screening process, you have the option of participating in the study.

You need to know that:

- Your participation is voluntary, that is, it is entirely up to you whether you choose to participate in this study or not.
- You may withdraw your consent to participate at any time for any reason without penalty.

If you decide to participate in the study, you will come back into the clinic for

Day 0, Vaccination Visit:

- You will have your vital signs measured (weight, blood pressure, temperature, heart rate, respirations) by a member of the outpatient staff.
- Your medical history will be updated, and you will have a targeted physical exam, and blood and urine collected for testing prior to giving you the vaccination.
- Risk-reduction counseling including safe-sex and pregnancy avoidance counseling will be performed at every visit.

- Females of childbearing potential will have a pregnancy test performed at all study visits. If a woman becomes pregnant during the study, she will be discontinued from the study.
- A total of 6.5 ml (~1⅓ teaspoons) of blood will be drawn for routine bloods and 81 ml (~5 ¼ tablespoons) of research blood for a total of 86.5 ml (~6 tablespoons) will be obtained.
- You will receive a single injection of influenza virus vaccine by IM injection (injection into a muscle in your arm).
- After receiving the vaccination, you will be asked to remain in the outpatient clinic for 20 minutes to monitor you for any allergic reaction to the vaccination.
- If for medical reasons, your primary care provider (PCP) requests that you start a new medication, please contact a member of the study team with the name of the new medication and reason you are being asked to take it.
- Before leaving the outpatient clinic, the study team will give you an appointment for your next clinic appointment.

Follow-up Visits: Day 7 and Week 3

- After receiving your vaccination, you will be asked to return to the outpatient clinic in 1 week for a safety check, to have research blood drawn and to have a symptom-targeted exam. Research blood will also be drawn again at the final study visit on week 3 (+/- 3 days). The maximum total amount of blood that will be drawn over the course of the study is about 220 ml (~14½ tablespoons) over 3 weeks.

A New York State-approved laboratory will perform standard laboratory tests during the research study. We will tell your doctor and/or you about any test results that may affect your health.

Laboratory testing conducted on your blood or tissues during the research study will fall into two general categories, 1) New York State-approved tests, and 2) experimental tests that have not been certified by New York State.

We will tell you or your doctor about any tests related to the research protocol that are performed by a New York State-approved laboratory, if the results may affect your health or safety.

By law, we cannot tell you or your doctor the results of experimental tests, that is, tests that have not been approved by New York State for diagnosis or treatment; however, if we find anything from experimental tests that might be important for your health, we may suggest that you have additional tests performed by a New York State-approved laboratory.

In this study, you will not receive routine care for any other medical conditions you may have.

Your medical information and test results will be written in your Hospital chart. The researchers or the Sponsor of the study may also keep separate records with information about you and your study tests.

Sometimes we will need to look at your earlier medical records. We will ask you to sign a form that will let health care providers share your records with us. This could be your doctor, a clinic or another hospital where you have been treated before.

III. What are the risks of taking part in this research study?

There may be some risks and discomforts in taking part in this study. We know that these risks and discomforts may happen during this study:

Blood draw: the risks associated with a blood draw are generally minor. They are mild pain at the needle site (common), local bruising at needle site (rare), infection and fainting (extremely rare).

Influenza Vaccine (IM administration):

- Most common injection-site reactions were injection site tenderness, pain, swelling and arm stiffness
- Most common systemic adverse events were headache and body aches (myalgia)
- If Guillain-Barre syndrome (GBS) has occurred within 6 weeks of previous influenza vaccination, the influenza vaccination will not be administered
- You will receive a Vaccine Information Sheet from the U.S. Centers for Disease Control and Prevention (CDC) which provides you with detailed information on "What you need to know" about the flu vaccine.

An additional risk for all vaccines is that the vaccine will not be effective.

Privacy Risks: There is the risk that there could be computer security breaches which could reveal your identity. There may be the risk that data about you may become public and could be used by employers or law enforcement agencies. These privacy risks are described in greater detail below.

There may be other risks and discomforts that we do not know about now, but we will tell you any new information discovered which might affect your decision to participate or remain in the study.

IV. What are the alternatives to participating in this research study?

You may choose not to participate in this study.

V. What are the benefits of taking part in this research study?

The benefits you might expect from taking part in this research study are cost-free vaccination against seasonal influenza, which has been shown to decrease the incidence of disease.

VI. Who will be able to see the information learned about you in this research study?

We will keep your personal information private and will do our best to keep this information confidential. We will listen to what you say we may do with this information, and we will follow the law. For example, by New York State law, hospitals must inform the New York State Department of Health if we find that you have a reportable communicable disease, such as a sexually transmittable disease, like chlamydia, hepatitis, gonorrhea, syphilis and HIV-1. Also, the researchers must report to the authorities if they believe that child abuse or neglect has happened, or to prevent serious harm to you or others.

Whenever possible, data about you will be unlinked from your name and identified by a code. However, auditors and regulators from government agencies that oversee research, and people at the Rockefeller University Hospital and at Rockefeller University may see your information in the course of their duties.

During this study, only the researchers will know that your samples came from you, because your stored samples will be identified only by a special code instead of your name. As a result, others who study your samples will not know that they came from you and will not be able to figure out that they came from you.

If the researchers publish the results of this study, they will not mention your name or other information that could identify you.

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

VII. What are the payment arrangements?

There is no cost to you for being in this research study.

You will receive $25 for the screening visit. At the vaccination visit you will receive $100 for your time and travel costs. You will receive $100 at each of the two follow-up visits. Payment will be made to participants who fill out a brief form with tax identification information from The Rockefeller University Finance Office and are eligible for and want to receive payment. Your information will remain confidential. If you do not want to complete the form, you can still participate in the study but will not be eligible for compensation.

If research using your samples helps develop a drug or another product that is sold to the public, the drug company, the University and the researcher may share in some of the profits. For example, a cell line from your samples could be used to make a product for sale. There are no plans to pay you any money resulting from such discoveries. However, by signing this form, you do not give up any rights you may have.

VIII. What happens if you don't want to stay in this study or your participation is ended?

You can choose if you want or do not want to be part of this study. If you do not join, there is no penalty, and no one will hold this against you. If you decide to join this study, you may change your mind and stop taking part in the study at any time, and this will not be held against you. Information about you up to that time may stay a part of the study.

During this study, the researchers may learn new information that might make you change your mind about whether you want to stay in the study. You will be given that information promptly.

If you decide to join the study now but later want to stop, you should let the researcher know.

The researchers also may stop you from taking part in this study, even if you do not choose to stop being in it. You may be asked to leave the study if:

- you fail to keep clinic appointments
- termination or cancellation of the research study by the investigator or the Rockefeller University Institutional review Board (RU IRB)

- there is a significant adverse event to the participant or to others in the study

If you stop or if you cannot finish the study for any reason, we will pay you for the part of the study that you have finished.

IX. Consent to the use, storage and sharing of your samples and data for separate research studies

The scientific value of your samples and the information obtained from them is greatly increased if we can share them with other scientists at universities and pharmaceutical or technological companies worldwide. Your samples and information will be used for biomedical research including genetic analyses. You will not be provided details of any specific research studies or their purpose. In general identifiers will be removed from the identifiable private information or identifiable biospecimens. Thereafter the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative. The genetic information obtained from your DNA is called genotype. The information about your disease condition and the physiology of your cells is called phenotype. May we:

- store, use, and share for many years your biospecimens and information including genotype and phenotype data, with other investigators at Rockefeller and elsewhere, possibly worldwide, and including pharmaceutical and technology companies, sample and/or data banks/repositories for separate studies for many years? Your biospecimens will either be stripped of information identifying them as yours or coded (we will hold the key to the code) so that they cannot be identified as having come from you. Other data related to your biospecimens, but that does not identify you, may accompany the specimens; and

- put anonymous data information from the analyses in a completely public database, available to anyone on the Internet; and

- put your coded genotype and phenotype medical data information and data information from more detailed analyses of your coded samples in a NIH controlled-access database/repository. The information in this database/repository will be available only to qualified researchers from academic institutions and commercial organizations, both domestic and foreign who have received approval from an NIH Data Access Committee?

Yes _____ No _____

If you say "No" you may still participate in this study.

Any time in the future, you may withdraw your consent to use any samples that have not already been used in research or shared. If you withdraw your consent, the remaining unused samples will be destroyed, unless the samples cannot be identified as having come from you. Data generated using your samples will continue to be used.

X. Who do you call if a medical problem results from this research study?

If you believe that this study has led to a medical problem, you should call the researcher listed below right away. The researcher will help you get appropriate, available medical care.

Name: Arlene Hurley, ANP, CCRC
Phone: 212-327-7433
Fax: 212-327-7373
E-mail: hurleya@rockefeller.edu

The Rockefeller University does not plan to pay for medical care that you may have as a result of taking part in this study at The Rockefeller University Hospital. However, you do not give up any rights you may have to seek compensation by signing this form.

XI. Who do you contact if you have questions about the research study?

Please ask as many questions as you want about this research study and this consent form. If you agree to take part in this study and have questions later, contact the following researcher:

Name: Arlene Hurley, ANP, CCRC
Phone: 212-327-7433
Fax: 212-327-7373
E-mail: hurleya@rockefeller.edu

If you have any concerns about your experience while taking part in this research study, you may contact The Rockefeller University Institutional Review Board (IRB) Office at (212) 327-8410, or the Office of Clinical Research at (212) 327-8408.

XII. May we have permission to contact you about future studies?

May we contact you by phone to find out if you are interested in hearing about new research studies? Contact would be made by the Rockefeller staff of the Clinical Research Support Office for Recruitment. If you decide at any time that you no longer want to be contacted, please tell us, and we will stop calling you.

Would you like us to contact you about future research studies?

Yes _____ No _____

If you say "no" to this question, this will not affect your participation in this study.

AGREEMENT TO PARTICIPATE -- SIGNATURES REQUIRED

I have read this consent form, and my questions have been answered.

A copy of this consent form will be given to you. Please keep a copy of the form as it contains important information that you may wish to refer to during the research study and thereafter.

I hereby voluntarily consent to take part in this research study.

Name of the Study Participant (Print) _____

_____ _____
Signature of Study Participant **Date (To Be Filled in by Study Participant)**

ALTERNATE SIGNATURE BLOCK

Participant requires assistance by a translator

Translation Services Provided by (choose one, by checking one box below):

☐ **Pacific Interpreters**

_____ _____
Language **Translator Identification Number**

Witness to telephone translation: _____
(Print Name)

_____ _____
Signature of witness **Date**

☐ **Other Translator:**

_____ _____
Name of translator **Date**

Witness to oral presentation: _____
(Print Name)

_____ _____
Signature of witness **Date**

Signature of the Person Conducting the Informed Consent Discussion

I have explained the research protocol and this consent form to the participant and have answered the participant's questions about this research study and/or the consent process.

Name of Person (Print) _____

_____ _____

Signature of Person Discussing Consent | **Date (To Be Filled in by Person Discussing Consent)**