Clinical Investigation Consent Form IRB Rev 2012

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You are being asked to join a research study, which will take place at The Rockefeller University Hospital. This form tells about the research. You should ask questions of the person who is explaining this form to you. After you feel that you understand the research and 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.

If you join the research study, you will take part for about 12 weeks (this includes screening). Certain groups will be asked to participate for up to 1 year. The research study as a whole will last about 1.5 years.

About 100 people will take part in the research study at the Rockefeller University Hospital.

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

I. <u>What this research study is about, and the reason for doing this research.</u>

Researchers at the Rockefeller University Hospital are doing this study 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 you receive will depend on the phase that the study is in when you enroll. You will be told what vaccine you are receiving.

After you receive the vaccine, you will be asked to return to the clinic every few weeks to give a sample of blood so that researchers can monitor your body's immune response. Your participation in the study will end 12 weeks from the day you are vaccinated.

You may volunteer to be in this study if you are a healthy adult between the ages of 18 and 80, with no medical conditions, have no allergies to eggs or any allergies to any of the vaccines to be administered in this study and have not received the influenza vaccine within the last month and not received a pneumococcal or meningococcal vaccine within the last 4 years. 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 12 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.

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 or not 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 be asked questions about your general health and your sexual behavior;
- A medical history and physical exam will be performed;
- You will be given pre-HIV testing counseling including 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;
- Up to 25 ml (1.5 tablespoonfuls) of blood will be drawn to test for Hepatitis B, Hepatitis C, pregnancy, chemistries, a complete blood count, and other health conditions;
- 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;

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, height, blood pressure, temperature, heart rate, respirations) by a member of the outpatient staff.
- A medical history will be taken, a physical exam performed, 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 almost 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 170 ml (~11 1/2 tablespoons) of research blood will be obtained.
- You will receive a single injection of influenza virus vaccine either by IM (injection into a muscle in your arm) or ID (injection under the skin in your upper arm) or intranasal, a pneumococcal vaccine by IM injection or a meningococcal vaccine by IM injection.
- 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.

<u>Day 3-4 Telephone Contact</u>

- On day 3-4 after vaccination, you will receive a telephone call or an email from a member of the research team to see how you are feeling and to find out if you had or are having any reactions to your vaccination. If you are experiencing any moderate or greater side effects, you will be asked to return to the outpatient clinic for an evaluation of your symptoms

<u>Follow-up Visits: Weeks 1, 3, 5, 7, 9 and 12</u>

- 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 at 3, 5, 7, 9, and 12 weeks (+/- 3 days). The maximum total amount of blood that will be drawn over the course of the study is 615 ml (~41 ½ tablespoons) over 12 weeks. At no time will the total volume of blood collected exceed 550 ml (36⅔ tablespoons) within an 8-week period.

Follow-up Visit for Groups 1 and 2 ONLY: 6-12 Months after Day of Vaccination (Day 0)

- Subjects in Groups 1 and 2 (Fluzone ID <65 years of age and Fluzone IM < 65 years of age) will be asked to return to the clinic for an additional visit to the outpatient clinic between 6 and 12 months from their Day of Vaccination. This visit will include vital signs, any updates to their medical/vaccination history, as well as a research blood draw of 23.5 ml (1 ½ tablespoons).

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.

This is a research study and, by law, we cannot tell you or your doctor the results of experimental tests. However, if we find anything that may be important for your health, we may suggest that you have tests done by a New York State-approved laboratory.

In this study, you will not receive care from the Rockefeller University research team for any medical conditions you may have.

Your medical information and test results will be written in your Hospital chart. The researchers 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 your 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 a research study. We know that these risks and discomforts may happen during this research 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

- The side effects are described in greater detail in the package insert.

Influenza Vaccine (ID administration):

- The most common injection-site reactions were redness (erythema) hardness (induration) , swelling , pain , and itching (pruritus) . Redness, hardness, swelling and itching, occurred more frequently following intradermal administration.
- The most common solicited systemic adverse events were headache, body aches, , and a general feeling of illness (malaise)
- If Guillain-Barre syndrome (GBS) has occurred within 6 weeks of previous influenza vaccination, the influenza vaccination will not be administered.
- The side effects are described in greater detail in the package insert.

Influenza Vaccine (Flumist live intranasal administration):

- The most common solicited adverse reactions were runny nose or nasal congestion and sore throat. Other possible side effects are cough, chills, tiredness/weakness and headache.
- If Guillain-Barre syndrome (GBS) has occurred within 6 weeks of previous influenza vaccination, the influenza vaccination will not be administered.
- The side effects are described in greater detail in the package insert.
- Those receiving Flumist should not be in close contact with those with a weakened immune system as they could cause an infection in those individuals.

Meningococcal Vaccine (Menveo):

- Common adverse events in individuals 2 through 55 years of age were injection site pain, redness, hardness, , and swelling; decreased appetite (anorexia) and loose stool (diarrhea)
- Other common solicited adverse events were headache, tiredness (fatigue), general feeling of illness, and stiff joints (arthralgia) (11-55 years of age)
- Individuals previously diagnosed with Guillain-Barre syndrome (GBS) will not receive Menveo vaccine.
- The side effects are described in greater detail in the package insert.

Meningococcal Vaccine (Menomune):

- Common adverse events in persons 11 to 55 years of age were pain, redness, and hardness, at the injection site, headache, tiredness, general feeling of illness, stiff joints, and loose stool

Pneumovax Vaccine (Pneumovax 23)

- The most common adverse reactions, reported were: injection-site pain/soreness/tenderness, injection-site swelling/hardness, headache, injection-site redness, weakness (asthenia) and tiredness, and body aches.

Pneumovax Vaccine (Prevnar):

- In adults aged 50 years and older the commonly reported solicited adverse reactions were pain at the injection site, tiredness, headache , muscle pain, joint pain, decreased appetite, injection site redness, injection site swelling, limitation of arm movement,

chills or rash.
- The side effects are described in greater detail in the package insert.

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

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

The benefits of participation are cost-free vaccination against seasonal influenza, pneumococcal bacteria or meningococcal bacteria - all of the vaccines in this study have been shown to decrease the incidence of disease. Also, information that we gain from this study may help others in the future.

V. 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(s), such as sexually transmittable diseases like chlamydia, hepatitis, gonorrhea, syphilis and HIV-1 infection.

We will share information about you only with government agency that oversees this research, and the people at the Hospital and the Rockefeller University in connection with their duties.

During the research 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, the 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."

VI. What are the payment arrangements?

At the vaccination visit you will receive $75 for your time and travel costs for being in this study. You will receive $35 for the follow-up visits except for your final study visit when you will receive $75 for completing the study. Patients who are asked to return 6-12 months after their Day of Vaccination (Day 0) will be paid $50. Payment will be made to participants who fill out a form from the Rockefeller University Finance Office and are eligible for and want to

receive payment.

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.

VII. What happens if you withdraw from the research study or your participation in the study 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 this 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 this study but later want to stop, you should let the researchers 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:

- failure to keep 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

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

May we store, use and share your blood/or tissue samples and data with other investigators at the Rockefeller and elsewhere for separate studies for many years? Your samples 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 sample, but that does not identify you may accompany your samples.

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.

Would you like us to store, use and share your blood/or tissue samples/associated data as described above?

Yes_____ No_____

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

IX. Who do you contact 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 investigator will help you to get the appropriate, available medical care.

Name: Taia Wang, MD, PhD
Phone: 212-327-323
Cell No.: (347) 433-8242
Fax: 212-327-7319
E-mail: twang@mail.rockefeller.edu

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

X. 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 on, you may contact the following researcher:

Name: Taia Wang, MD, PhD
Phone: 212-327-323
Cell No.: (347) 433-8242
Fax: 212-327-7319
E-mail: twang@mail.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.

XI. 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)**