Informed Consent Form

WINSHIP4709-19: Influenza Vaccination in Plasma Cell Dyscrasias

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You Are Being Asked to Be in a Research Study
Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 175 people who are being studied at Emory.

Why is this study being done?
This study is being done to answer the question: can we improve influenza vaccinations in patients with plasma cell disorders. You are being asked to be in this research study to test one flu shot versus three flu shots in a single season.

Do you have to be in the study?
It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?
If you are eligible and want to be part of the study, you will participate for 3-5 study visits over approximately 5 months. The researchers will ask you to do the following: 1) Receive one OR three flu shots, one pneumonia vaccine (Prevnar) if you haven't already received it this year, and 3 blood tests. The flu shot(s) will be paid for by the study.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question.

What are the risks or discomforts I should know about before making a decision?
The study will take time. Flu shots can cause side effects, and receiving three flu shots over an approximate 4 month period may cause more of these side effects than a single shot. If you are randomly assigned to the group that gets three flu shots, this may not work any better than a single shot, and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include flu shot vaccine side effects (e.g. sore arm, fever, fatigue to name the most common), loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
You can receive a single standard flu shot at most doctor's offices or pharmacies.

Costs
You WILL NOT have to pay for any of the study procedures, in particular those that are not covered by your medical insurance. There is more information in the cost section below.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts are research and which are

standard care that you would have even if you did not join the study. Take time to consider this, and talk about it with your family and friends.

EMORY UNIVERSITY | Institutional Review Board
Research Administration

EMORY | WINSHIP CANCER INSTITUTE
A Cancer Center Designated by the National Cancer Institute

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: Winship 4709-19: Influenza Vaccination in Plasma Cell Dyscrasias

Principal Investigator: Craig Hofmeister, MD, MPH

Sponsor: Winship Cancer Institute of Emory University

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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.

What is the purpose of this study?

The purpose of this study is to improve influenza vaccination in patients with plasma cell disorders, e.g. monoclonal gammopathies, AL Amyloidosis, and myeloma. Although all patients are encouraged to have yearly influenza vaccinations, it is believed that vaccinations are less effective in these patients.

One of the questions we are evaluating is whether we can reduce influenza-related complications including infections, hospitalizations, and deaths. Because infections such as influenza may theoretically support the growth of tumor cells, we are also evaluating whether improving your protection against influenza can improve the status of your plasma cell disorder.

What will I be asked to do?

Most patients will be seen in clinic at Emory, receive this consent form, and be screened for this clinical trial all on the same day. If you are deemed eligible to participate and after appropriate consent, a research coordinator will record your symptoms, blood for research will be obtained, and you will be randomized to either receive a single flu shot, the control group, or 3 flu shots, the experimental group, during this flu season. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the researchers will choose the group to which you are assigned.

All patients will receive the high dose flu shot. This high dose vaccine is currently only FDA approved in patients 65 years or older. In an attempt to improve influenza vaccination, we will administer the high dose vaccine to all patients in the study regardless of age.

If you haven't received a pneumonia vaccine (Prevnar) this year, we recommend you receive it approximately one month after the flu shot. This will boost your protection against pneumonia.

The visit schedule is as follows:

Treatment arm	Visit 1	1 month	2 months	4 months	5 months
3 shots (Experimental arm)	Blood test Flu shot	Blood test Prevnar	Flu shot	Flu shot	Blood test
1 shot (Control arm)					

And these two arms can be compared as follows:

Treatment arm	Number of flu shots you'll receive this season	Number of visits required	Amount of research blood drawn for the entire 5 month study
3 shots (Experimental arm)	3	5	120 mL (approx. 8 tablespoons)
1 shot (Control arm)	1	3	

How will my flu shot be provided?

The flu shot that you will take will be dispensed by the pharmacy and delivered to the principal investigator or study team member. The principal investigator or health care providers on his/her research team will give you the shot. If you have questions about the flu shot, you should ask the study doctor or study nurse. You may also call the pharmacy at [redacted] if you have questions.

Who owns my study information and samples?

If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study.

What are the possible risks and discomforts?

There may be side effects from the flu shot that are not known at this time.

The most common risks and discomforts expected in this study are related to the flu shot. Side effects are generally mild and include soreness at vaccination site (10-64% of subjects) that lasts less than two days. When the vaccine is given, the subject may feel a slight pain and burning during the injection. Fever, fatigue and muscle aching can occur after vaccination.. These reactions begin 6-12 hours after vaccination and can persist for 1-2 days.

The less common risks and discomforts expected in this study are an allergic reaction. Very rarely, occurring in about 1 in 4 million people (0.000025%) given a vaccination, there can be a serious allergic reaction to a vaccine. These reactions can manifest as skin rash (hives), swelling, reactive airway disease like an asthma attack, fast hear beat, or low blood pressure. If these reactions occur, they can usually be stopped by the administration of emergency medications clinic staff.

A rare but possible risk - it is not known whether receiving more than one flu shot in a season increase the risk of Guillain-Barre syndrome (GBS), estimated at 2.84 per million doses (0.000284%). GBS is a rare disorder in which your body's immune system attacks your nerves. Weakness and tingling in your extremities are usually the first symptoms. These sensations can quickly spread, eventually paralyzing your whole body. Most people with the condition must be hospitalized to receive treatment. The exact cause of GBS is unknown, but it is often preceded by an infectious illness such as a respiratory infection or the stomach flu. There's no known cure for Guillain-Barre syndrome, but several treatments can ease symptoms and reduce the duration of the illness. Most people recover from Guillain-Barre syndrome, though some may experience lingering effects from it, such as weakness, numbness or fatigue.

The risk of blood draws. The physical risk of drawing blood is local pain and bruising at the site. Qualified phlebotomists or designees will draw blood samples. Care will be taken to obtain these specimens in a safe and hygienic manner. A small number of people experience lightheadedness or fainting. There is a slight risk of infection. To minimize these risks, attempts will be made to draw study blood samples at the same time as blood draws needed for routine clinical care are obtained. Repeated blood drawing may be associated with iron deficiency anemia.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

This study is not designed to benefit you directly. Your plasma cell disorder may improve while you are in this study but it may not, and it may even get worse. This study is designed to learn more about your response to the flu shot. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

You will not be offered compensation for being in this study.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. You can receive a single standard flu shot at most doctor’s offices or pharmacies.

The study doctor will discuss these options with you. You do not have to be in this study to receive a flu shot.

How will you protect my private information that you collect in this study?
Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information
De-identified data from this study (data that has been stripped of all information that can identify you), including your de-identified genetic information, may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data [and specimens] from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

Any specimens sent to Sanofi Pasteur will be destroyed after the blood has been analyzed to determine your response to the influenza vaccine.

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Medical Record
If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory Healthcare medical record you have now or any time during the study.

Tests and procedures done at non-Emory places may not become part of your Emory medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you believe you have become ill or injured from this research, you should contact Dr. Craig Hofmeister at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory will help you get medical treatment. Emory has not set aside any money to pay you if you are injured as a result of being in this study. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence. “Negligence” is the failure to follow a standard duty of care.

If you get ill or injured as the direct result of the study drug or a study procedure, then, depending on what insurance you may have, the sponsor may pay for some of all of the costs of your medical treatment for the illness or injury. If you are uninsured, or if you have Medicare or Medicaid, the sponsor will pay for the costs of your medical treatment for the illness or injury. If you have Medicare or Medicaid, the sponsor may need information about your identity and your study treatment to give to the government agencies that run these programs.

If you have private insurance, Emory will look at your claims for these costs to determine if they can be sent to your insurance for payment. Your insurer may be told that you are in a research study and given information about your treatment. The sponsor will pay for the costs that are not paid by your insurance provider.

The sponsor will not pay for co-payments or co-insurance that Medicare, Medicaid or your private insurer says you must pay. Also, the sponsor will not pay for illness or injury:

(a) from medical conditions you had before you started the study;
(b) from the natural progression of your disease or condition;
(c) from your failure to follow the study plan; or
(d) that is directly caused by the negligence of an Emory employee.

You will have to pay for any treatment costs that are not paid for by the sponsor or by any insurance you may have.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under “injury” as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor’s advice about how to go off the study treatment.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

The only reason why the researchers may stop your participation – if we discover that there are unexpected, significant, or unacceptable risks to patients receiving three flu shots in a single flu season.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- Winship Cancer Institute, Emory University is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The research team and the Sponsor may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Other researchers and centers that are a part of this study.
    - Government agencies that regulate the research including: Office for Human Research Protections; Food and Drug Administration.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

Craig Hofmeister, MD
Winship Cancer Institute of Emory University
1365B Clifton Road NE, Emory Clinic Building B
Atlanta, GA 30307

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information
Contact Dr. Craig Hofmeister, MD at [redacted]:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at [redacted]:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in the main study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____
Name of Subject

_____ _____ ___:___am/pm
Signature of Subject **Date Time (please circle)**
(18 or older and able to consent)

TO BE FILLED OUT BY STUDY TEAM ONLY

_____
Name of Person Conducting Informed Consent Discussion

_____ _____ ___:___am/pm
Signature of Person Conducting **Date Time (please circle)**
Informed Consent Discussion

Date Time