Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: **WU 445:** Longitudinal tracking of bone marrow plasma cell responses to licensed human vaccines

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This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant.

KEY INFORMATION

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 approximately 25 people who are being studied in this study.

Why is this study being done?
This study is being done to understand and measure how the immune system responds to and remembers different types of vaccines. To do this, four vaccines approved by the U.S. Food and Drug Administration (FDA) will be given simultaneously that you may or may not have had previously.

You are being asked to be in this research study because you are a healthy adult (18 years old or older) and you are willing to receive the yearly trivalent inactivated influenza vaccine (TIV), the tetanus, diphtheria, and acellular pertussis vaccine (Tdap), the nonvalent HPV (HPV) vaccine, hepatitis A virus (HAV) vaccine and undergo study procedures.

Do you have to be in the study?
It is your choice to join this research study. You do not have to be in it. If you decide to join this study, you can change your mind later and withdraw from the research study. Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?
If you qualify and choose to join the study, you will participate for up to 24 months (including up to 11 study visits). The researchers will ask you to do the following:

- Give information about medical history relevant to the study, including medications and vaccines you have received.
- Have your vitals (blood pressure, pulse) and temperature checked.
- Check your height and weight.
- Allow study health care providers to conduct physical exams.
- Receive the TIV, Tdap, HPV, and HAV vaccines.
- Have blood samples collected for immunologic tests and genetic analysis.

- Donate a small amount of bone marrow by needle aspiration at a maximum of seven visits.
- Complete information on a memory aid every evening for 7 days after vaccination.

The following additional procedures are optional:
- Donate bone marrow core biopsies, which can be performed at the same visits when completing the bone marrow aspirations.
- Allow clinicians to take an ultrasound of your lymph nodes and take fine needle aspirates of lymph nodes in both arm pits at a maximum of eight separate visits.

All costs for these procedures will be covered 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. This study is not intended to benefit you directly. However, you will receive the annual influenza vaccine, as recommended by the CDC. You will also receive a Tdap booster. These vaccines provide protection from dangerous illnesses. We will provide information on whether additional vaccines (for HAV or HPV) may be required in the future if you require full vaccination.

What are the risks or discomforts you should know about before deciding?
The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious.

Risks for this study include:
- Risks associated with local or generalized reactions to the study vaccines (mild to moderate flu-like symptoms, joint pain, joint swelling, redness, bruising or rash at injection site).
- Risks associated with medications used for pain and anxiety control during study procedures.
- Risks associated with blood draws.
- Risks associated with bone marrow aspiration (a procedure that takes out a small amount of bone marrow fluid through a needle).
- Risks associated with bone marrow core biopsy (a procedure that uses a slightly larger needle to remove a core of bone marrow to preserve the underlying architecture).
- Risks associated with fine needle aspiration biopsy (a procedure to obtain a sample of cells from a lymph node using a thin needle inserted through the skin).
- Loss of privacy.
- Breach of confidentiality.

You can find a full list of expected risks, their frequency and severity in the section titled “What are the possible risks and discomforts?”

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate.

Costs
You WILL NOT have to pay for any of the study procedures. There is more information in the “Costs” section further below.

What Should You 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 such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to think about this and talk about it with your family and friends.

The rest of this document provides more details about the study.

WHAT IS THE PURPOSE OF THIS STUDY?

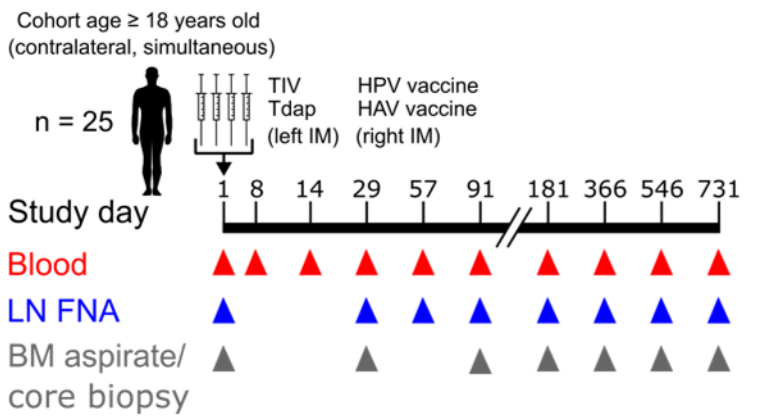
Vaccines help protect us from infectious diseases by teaching the immune system to recognize and respond to specific germs. One of the most important ways vaccines protect us is by generating long-lasting antibody-producing cells that live in the bone marrow. However, not all vaccines provide lifelong protection, and we still do not fully understand why some vaccine responses last longer than others.

The purpose of this study is to learn how long immune responses last after receiving four routine adult vaccines: the influenza vaccine (TIV), the Tdap vaccine (which protects against tetanus, diphtheria, and pertussis), the HPV vaccine (which helps prevent human papillomavirus infections), and the hepatitis A (HAV) vaccine. All of these vaccines are approved for routine use in adults and will be given together at one visit. You may have received these or similar vaccines before (such as Tdap) and others you may not have had before (e.g., HAV or HPV)

We will collect blood, lymph node samples, and bone marrow samples over a two-year period. This will allow us to track how the immune response develops and how long it lasts in different parts of the body. We hope this information will help researchers understand how to design better vaccines that provide longer-lasting protection.

WHAT WILL HAPPEN DURING THIS STUDY?

If you decide to join this study and sign this consent form, you will be asked a series of questions to determine your eligibility. If you qualify for the study, you will be one of the approximately 25 participants who will be enrolled in the study. The study will be conducted at the Washington University Infectious Disease Clinical Research Unit (ID-CRU). Lymph node sampling by fine needle aspiration (FNA) and bone marrow aspiration (BMA) and core biopsy (BMCB) will be conducted at Barnes Jewish Hospital (BJH) and/or Washington University School of Medicine (WU).



Screening visit

The study staff will review the informed consent form with you. After signing the informed consent, you will be assigned a unique study participation number. The following procedures will be performed:

- Collection of demographic information such as birthdate, age, sex/gender and race and/or ethnicity.
- Review of medical history including current medication use and vaccination history (including previous receipt of influenza, Tdap, HAV, and HPV vaccinations).
- Vital signs and targeted physical exam as indicated based on review of your health.
- Review of the study eligibility criteria.
- Collect urine to perform pregnancy test if you are of childbearing potential

You will not qualify to participate in the study if you meet any of the following exclusion criteria:

1) You have a history of severe allergic reaction to any component of the TIV, Tdap, HPV, or HAV vaccines, including allergic reactions to neomycin, yeast, or prior severe reaction after vaccination including anaphylaxis or encephalopathy within 7 days of vaccination.
2) You have a current or previous diagnosis of immunocompromising condition to include human immunodeficiency virus, immune-mediated disease requiring immunosuppressive treatment, or other immunosuppressive condition.
3) You have received systemic immunosuppressants within the last 6 months or will need to receive immunosuppressants during study participation.
4) You are currently pregnant or breastfeeding.
5) You are unwilling to use an effective method of contraception if you are of childbearing potential.
6) You have history of allergic or serious adverse reaction to other vaccines.
7) You have recently received or plan to receive an investigational or approved vaccine or investigational drug up to 28 days before or after receiving study vaccine.
8) You have received any 2025-2026 annual influenza vaccine.
9) You have received any quadrivalent inactivated influenza vaccine, TIV, Tdap, HPV, or HAV

vaccine in the prior 6 months before study vaccination.
10) You have received blood products or immunoglobulin products within the prior 3 months before study vaccination.
11) You are sick at time of your vaccination visit.
12) You have a history of Hepatitis B or Hepatitis C.
13) You have a history of any chronic clinically significant medical problem.
14) You have a history of excessive alcohol consumption, drug use, psychiatric conditions, social conditions, or occupational conditions that would affect your participation in the trial.

There are other exclusions that apply specifically for the bone marrow aspirates/core biopsies and lymph node aspirates notably allergy to anesthetics or taking medications that will affect the ability of your body to form clots after these procedures.

Bone marrow aspiration (about 30-60 minutes)
Bone marrow aspirates will be collected prior to vaccination and at other timepoints after vaccination. A maximum of 7 bone marrow aspirate procedures will be performed.

This is a procedure that is performed routinely in patients with diseases involving the bone marrow so that doctors can examine the cells in the bone marrow. We do not think that you have a bone marrow disease, but we would like to obtain a sample of normal bone marrow cells from you for research purposes. Prior to the bone marrow aspiration biopsy, the skin over your hip bone will be cleansed with a sterile solution. You will then receive an injection with a local anesthetic (a shot of painkiller) called lidocaine. You may feel a sharp sting and burn when the anesthetic numbs your skin over the injection site. The pain usually lasts for only a few seconds. Once the area is numbed well the biopsy needle will be inserted through the skin of your hip and quickly into the bone in order to enter the bone marrow cavity. You may hear a tapping sound and feel pressure when the needle enters the bone. A small amount of bone marrow (about 4-6 teaspoons of bone marrow cells) will then be suctioned with a syringe. You may feel a cramping sensation in your buttock and down your leg. This typically lasts 10 seconds or less. The cramping sensation stops right away after the aspirate is collected. The needle is then removed and the tissue inside the needle will be saved. Pressure is applied to the biopsy site to stop any bleeding, and a bandage is applied. The entire procedure should take about 5-10 minutes.

During a bone marrow aspirate, the following actions will take place:
- Review of your current health status.
- Undergo bone marrow aspiration procedure.
- Provide instructions to contact the study team if complications arise from the procedure.

This study will involve immunologic testing and gene expression testing via RNA sequencing. The results of these tests will not be shared with you. However, the results of the safety labs will be shared with you. Similarly, incidental findings that are identified on ultrasound examination will be disclosed and explained to you by the study investigator, who will provide a referral to the appropriate clinical specialist.

Optional Procedures:

Bone marrow core biopsy (about 15-20 minutes in addition to BMA)

Bone marrow core biopsies are optional and may be performed at the same time as a scheduled bone marrow aspirate. A maximum of 7 core biopsies may be collected during the study.

The procedure occurs while completing the bone marrow aspiration. Prior to the bone marrow core biopsy, the skin over your hip bone will be cleansed with a sterile solution. You will then receive an injection with a local anesthetic (a shot of painkiller) called lidocaine. Once the area is numbed well, the biopsy needle will be inserted through the skin of your hip and into the bone in order to enter the bone marrow cavity. Core biopsies 1/16 inch in diameter and 1⁄2-1 inch long bone marrow tissue will then be collected in the needle. The needle is then removed and the tissue inside the needle will be saved. Pressure is applied to the biopsy site to stop any bleeding, and a bandage is applied. The entire procedure should take about 5-10 minutes. You may feel a sharp sting and burn when the anesthetic numbs your skin over the injection site. You may hear a crunching sound and feel pressure and some pain when the needle enters the bone. The pain usually lasts for only a few seconds. If you have any serious symptoms, you may need to return to the clinic for a doctor's examination.

During a bone marrow core biopsy visit, the following actions will take place (in conjunction with BMA above):

- Review of your current health status.
- Undergo bone marrow core biopsy procedure.
- Provide instructions to contact the study team if complications arise from the procedure.

Please place your initials in the blank next to Yes or No:

I agree to undergo the BMCB procedure.

_____Yes _____ No
Initials Initials

Lymph node sampling by fine needle aspiration (FNA) (about 120 minutes):

Lymph node aspirates are optional and will be collected prior to vaccination and at other timepoints after vaccination. You will complete no more than a maximum of 8 FNA procedures.

Fine Needle Aspirate procedures will be performed at BJH and/or WU.

Your lymph nodes will be assessed for accessibility and proximity to blood vessels with an ultrasound, and one will be selected for sampling. The skin over the target lymph node will be cleansed with a sterile solution. You will receive an injection with a local anesthetic (a shot of painkiller) called lidocaine. An FNA pass is then made with a new 25-23-gauge needle. A pass involves advancement of the FNA needle into the cortex of the lymph node, after which it is pushed and pulled back and forth through the lymph node multiple times. Each forward push is a needle throw. Each pass consists of

multiple throws (as many as 60) and usually lasts approximately 15 seconds. As throws are made, cells and fluid from the lymph node are collected inside of the needle. This process is repeated for a total of 6 passes, using 6 separate FNA needles. After each pass, the needle is removed and handed to a member of the research team who processes the sample. Additional passes beyond the routine 6 are sometimes but rarely necessary if the withdrawn material is scant. The procedure will then be repeated on the opposite side. In the event that the research staff are unable to locate a suitable node for FNA, you may still participate in the study.

During a fine needle aspiration, the following actions will take place:

- Review of your current health status.
- Obtain vital signs.
- Undergo lymph node ultrasound and fine needle aspiration sampling procedure on both the right and left axilla.
- Provide instructions to contact the study team if complications arise from the procedure.

Please place your initials in the blank next to Yes or No:

I agree to undergo the FNA procedure.

_____ Yes **_____ No**
Initials **Initials**

You may elect to withdraw from FNA or BMCB sampling at any point and still remain in the study**.**

Vaccination Visit (D1) (about 60 minutes)
During the vaccination visit, the following actions will take place:

- Review heath status and any changes in medical and vaccination history and medications.
- Review the eligibility criteria.
- Obtain vital signs.
- Collect a pregnancy test if you are a person of childbearing potential
- Collect blood to test your immune system (3-4 tablespoons).
- Vaccination:
    - Review the Vaccine Information Sheets for the TIV, Tdap, HPV, and HAV vaccines.
    - Get the vaccinations
        - TIV and Tdap will be given intramuscularly in the left arm
        - HPV and HAV will be given intramuscularly in the right arm
    - Wait for 30 minutes in case of any immediate reactions.

Follow-up Visits (D8, D14, D29, D57, D121, D181, D366, D546, and D731)
You will return for follow-up visits. At 8 of these visits, you will have your blood drawn (3-4 tablespoons), we will review your current health status and note any changes in health history since the screening visit, including current medication use and vaccination history.

The six additional bone marrow aspirates will be repeated at D29, D91, D181, D366, D546, and D731.

The optional bone marrow core biopsy will also be repeated at that time.

Up to seven separate visits will be scheduled for the follow-up lymph node aspirates (D29, D57, D91, D181, D366, D546, and D731)

You will complete a memory aid for 7 days after vaccination to tell us more about any expected reactions to vaccination.

How will your study drug be provided?
The study vaccines that you will take will be dispensed by the ID-CRU pharmacy and delivered to the study team. The research team will provide the study vaccine to you. If you have questions about the study vaccine, you should ask the principal investigator or study nurse.

Note: The research team for this study includes non-licensed team members who may obtain your consent or help guide you through the study. There are some kinds of questions only licensed clinicians can answer. If you have questions like these, the non-licensed coordinator will ask a licensed study team member to answer your questions**.**

Will you save my research information and/or biospecimens to use in future research studies?

The data and samples we are obtaining in this study may be made available for studies going on right now as well as studies that are conducted in the future. These studies may be done by researchers at Washington University, other research centers and institutions, or private companies involved in research.

We may also share your research data with large data repositories (a repository is a database of information) for use by others, such as the research community, institutions, private companies, and the general public. If your individual research data is placed in one of these repositories, your name and other identifying information will be removed. All reasonable precautions will be taken to protect your privacy and confidentiality. Necessary approvals will be obtained to use the data. Certain summary information may be available to the general public.

These future studies may provide additional information that will be helpful in understanding influenza, tetanus, diphtheria, pertussis, HPV, hepatitis A or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. Should this occur, there are no plans to provide financial compensation to you. There are no plans to provide financial compensation to you should use of your data and samples occur. It is unlikely that what we learn from these studies will have a direct benefit to you. By allowing us to use your data and samples you give up any property rights you may have in the data and samples. We will protect the confidentiality of your information to the extent possible.

This future research may include genetic research. Genes are a unique combination of molecules (called DNA) that we inherit from our parents. There are millions of tiny differences in our genes that determine things like our height or the color of our eyes. Some of these differences may make some people more or less likely to develop certain diseases or conditions or to have certain characteristics. The future genetic research may include looking at the difference in genes between different groups of people. It may also

include whole genome sequencing, which involves studying your entire DNA sequence. This type of testing creates information that is as unique to you as your fingerprint.

Your data and samples will be stored without your name or any other kind of link that would enable us to identify which sample(s) or data are yours. Therefore, it will be available indefinitely for use in future research studies without your additional consent and cannot be removed.

HOW LONG WILL I BE IN THIS STUDY?

If you qualify and choose to join the study, you will participate for up to 24 months. There are 11 planned visits. In order to accommodate scheduling, some visit events may need to be scheduled on separate days.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

The most common risks and discomforts expected in this study include:

Influenza vaccine (TIV):
Common mild to moderate risks of vaccination with the flu vaccine may include: soreness, redness, or swelling at the injection site; headache; low-grade fever; fatigue; muscle aches; and nausea. Rarely, neurologic conditions such as Guillain-Barré syndrome (temporary nerve weakness or paralysis) have been reported. Although highly unlikely, injections into the muscle can result in muscle damage, bruising, or injection site infection. The vaccine will be administered by experienced and trained staff using aseptic technique to minimize or avoid these risks. Severe reactions to components of the vaccine are possible but extremely rare. We will observe you for allergic reactions after vaccination and will treat allergic reactions if they occur.

Tdap vaccine:
Common mild to moderate risks of vaccination with the Tdap vaccine may include: pain, redness, or swelling at the injection site; mild fever; headache; body aches; tiredness; and upset stomach. Some individuals may also experience chills or rash. Rarely, inflammation of a nerve (brachial neuritis) has been reported. As with all intramuscular injections, there is a very small risk of muscle injury, bruising, or infection. The vaccine will be given by trained personnel using sterile technique. Severe reactions to components of the vaccine are possible but extremely rare. We will observe you for allergic reactions after vaccination and will treat allergic reactions if they occur.

HPV vaccine:
Common mild to moderate risks of the HPV vaccine may include pain, redness, or swelling at the injection site; headache; fatigue; nausea; dizziness; and fainting, especially in adolescents and young adults. Some individuals may experience muscle aches or fever. Although rare, more serious allergic reactions can occur. As with all intramuscular injections, there is a very small risk of muscle damage,

bruising, or infection. The vaccine will be administered by trained staff using sterile technique. Severe reactions to components of the vaccine are possible but extremely rare. We will observe you for allergic reactions after vaccination and will treat allergic reactions if they occur.

Hepatitis A vaccine (HAV):
Common mild to moderate risks of the hepatitis A vaccine may include soreness or tenderness at the injection site; headache; tiredness; muscle aches; and low-grade fever. Gastrointestinal symptoms such as loss of appetite or nausea can occasionally occur. As with all muscle injections, there is a small risk of bruising, muscle irritation, or infection at the injection site. The vaccine will be administered by experienced personnel using sterile technique. Severe reactions to components of the vaccine are possible but extremely rare. We will observe you for allergic reactions after vaccination and will treat allergic reactions if they occur.

For all four vaccines there are extremely rare side effects:
Anaphylaxis – a serious life-threatening allergic reaction
Fever greater than 102.7°F

Risks associated with medications used for pain control during study procedures:

a) Lidocaine
b) Complications of lidocaine (1% or 2%) injection used for local anesthesia are rare, mostly seen if a major vessel is inadvertently injected or the recommended dose is exceeded. The immediate side effects are related to:
    a. lightheadedness, confusion, tinnitus (ringing or buzzing in the ear), blurred or double vision, vomiting, numbness, twitching, tremors, convulsions, unconsciousness, slow and ineffective breathing, and interruption of breathing.
    b. Decreased myocardial contractility (ability of the heart muscle to contract), vasodilation (dilatation of blood vessels, which decreases blood pressure), arrhythmias (irregular heart rhythm) and cardiac arrest.
    c. Allergy to lidocaine either immediate (urticaria or anaphylaxis) or delayed (contact dermatitis) has been described. You will be monitored after any procedure.

Risks of study procedures:

Blood draws
Some people may get lightheaded or faint during or just after having blood drawn. Having your blood drawn can be painful and can cause bruising. Bruising can be prevented or reduced by putting pressure on the site for a few minutes after the blood is drawn. It is possible to get an infection where the study doctor or study staff drew your blood, but this is very rare. To reduce the risk of infection, the study doctor or study staff will wipe the area clean with alcohol and use sterile equipment.

Fine needle aspirate of lymph node
The potential risks for fine needle aspiration are rare. They include but are not limited to:

- Tenderness around the aspiration site.
- Bruising around the site.

- Bleeding around the site.
- Hematoma formation around the site (blood collection under the skin).
- Much rarer complications include:
  - Infection of the site.
  - Fainting
  - Numbness caused by accidental nerve damage.
  - Collapsed lung.

Bone marrow aspirate

The physical risks of bone marrow aspiration may last 1 to 3 days, the risks are:

- Tenderness around the aspiration site.
- Bruising around the site.
- Bleeding around the site.
- Hematoma formation around the site (blood collection under the skin).

Rare but more serious side effects include:

- Damage to normal blood vessels, veins, or bone structures.
- Numbness caused by accidental nerve damage.
- Very rarely localized infection at the site.
- Lightheadedness, nausea, and transient low blood pressure.
- Infection at site

Risk of Concomitant Medications, Prophylactic Medications and Rescue Medications

We do not anticipate the use of any other medication; however, should severe allergic reactions occur, epinephrine (1:1000) and diphenhydramine injections are readily available.

- Epinephrine injection can be associated with high blood pressure, arrhythmia, lightheadedness, nervousness, restlessness, tremor, shortness of breath and diaphoresis (cold sweats/excessive sweating). The frequency of these side effects are not defined.
- Diphenhydramine injection may be required to treat possible allergic reactions and its use can be associated with low blood pressure, arrhythmia, confusion, dizziness, sedation, restlessness, diarrhea, nausea, and urinary retention. The frequency of these side effects is also not defined.

If you are a person capable of becoming pregnant, we will ask you to have a pregnancy test before beginning this study. You must use effective birth control methods and try not to become pregnant while participating in this study. If you become pregnant, there may be unknown risks to your unborn child, or risks to your unborn child that we did not anticipate. There may be long-term effects of the treatment being studied that could increase the risk of harm to an unborn child. You must tell the doctor if your birth control method fails while you are on the study. If you believe or know you have become pregnant while participating in this research study, please contact the research team member identified at the top of this document as soon as possible. Please discuss with the research team how long you need to wait before becoming pregnant after completing the treatment or procedures on this study.

Risks of Genetic Research
There may be information obtained from the genetic testing that indicates that you, or potentially a family member (since we inherit genes from our parents and pass genes on to our children) are at risk for a particular disease or condition. For example, genetic sequencing may indicate that an individual is more prone to develop certain types of cancer or other types of diseases, (e.g., Alzheimer's or other inherited diseases).

While the data developed for this study is being stored without traditional identifiers (stored only with coded ID numbers, no names), there may be ways of linking the genetic materials back to you. Because your DNA is unique to you, it is possible that someone could look at the information in the DNA database and compare it to information in another database and use that to identify you. This is difficult to do and is very unlikely to happen.

If made available to persons or agencies outside of our research group, information about genetic test results could affect your employment or insurance. For instance, employers, insurers, or others may use this information when making decisions about you or your family members regarding employment, insurance, or other benefits.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans and employers with greater than 15 employees to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance or long term-care insurance.

Breach of Confidentiality
One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether to be in this study, your doctor will discuss the other options that are available to you. If you choose not to join this study, you can receive the TIV, Tdap, HPV, or HAV vaccines outside of this study. You do not have to be in this study to receive the vaccinations.

If you choose to join this study, you may not be able to join other research studies. Discuss this with the researchers if you have concerns. You may wish to look on websites such as clinicaltrials.gov and ResearchMatch.org for other research studies you may want to join.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will be asked to provide your social security number (SSN). You may also need to provide your address if a check will be mailed to you.
You will receive:

- $50 for each completed study visit. (max of 11)
- $75 additional for the vaccination visit (1)
- $125 for each bilateral FNA (max of 8)
- $125 for each BMA (max of 7)
- $100 for each BMCB (max of 7)

You will complete no more than 8 lymph node fine needle aspirations and no more than 7 bone marrow aspirations and bone marrow core biopsies. We compensate you for your time and travel. We can also support you with additional travel costs on a case-by-case basis. If you do not finish the study, we will compensate you for the visits you have completed. You will get up to $3200 in total if you complete all study visits. All compensation will be through the Advarra Participant Payments system via the Center for Clinical Studies. The system provides payment on a reloadable VISA debit card. You will be provided with information about any fees and how to use this debit card.

WHO IS FUNDING THIS STUDY?

The University and the research team are not receiving payment from other agencies, organizations, or companies to conduct this research study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at Dr. Patrick Olson, MD, PhD at 314 454-0058 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about whether payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

Other people such as those listed below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you. We will keep your participation in this research study confidential to the extent permitted by law.

- Government representatives (including the Office for Human Research Protections) to complete federal or state responsibilities.
- The U.S. Food and Drug Administration

- The National Institutes of Health (NIH)
- Your primary care physician if a medical condition that needs urgent attention is discovered.
- Hospital or University representatives to complete Hospital or University responsibilities
- Information about your participation in this study may be documented in your health care records and will be available to anyone with access to your health care record, including your health insurance company. This information may also be released as part of a release of information request.
- The last four digits of your social security number may be used in hospital or University systems to track billing information for research procedures.
- Advarra operates the Advarra payment system and uses the personal information listed above to put study payments onto the card.
- Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and the Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

To help protect your confidentiality, we will assign the information you give us a code number.

- Electronic records (computer files, electronic databases, etc.) - Any computer data is accessible only by passwords which are changed every 90 days.
- Blood and urine samples – Initially labeled only with ID number, gender, date of birth, and date and time of collection, then barcode that has no identifying information on it.
- FNA and bone marrow samples labeled only with ID number, gender, date of birth, and date and time of collection,
- Paper/hard copy records (hard copy surveys, questionnaires, case report forms, etc.) - Patient information is given a code number. A master list linking the code number and your identity will be kept separate from the research data. Only the Principal Investigator and people helping him will be able to see the list. Kept in locked, security controlled environment.

If you receive Medicare benefits, are injured as part of your participation in this research study and medical treatment relating to this injury is paid by anyone other than you or your insurance company, that payer will need to collect personal information about you. This information includes your name, date of birth, gender, social security number, Medicare identification number and information related to this research study. The payer will report this information to the Centers for Medicare & Medicaid Services (CMS), the federal agency that oversees the Medicare program, during your participation in the study and for as long as the payer is required by CMS to report this information. If you do not want to release your personal or treatment related information you have the right to refuse reimbursement by the payer for any research injury. The payer will not use this information for any other purpose.

Research monitors, auditors, the study sponsor, the Institutional Review Board, and other regulatory authorities will be granted directed access to your original health care record to verify the conduct of the clinical trial procedures and/or data. This access will be permitted to the extent permitted by the

applicable laws and regulations without violating the confidentiality of your information. By signing this form you are authorizing such access.

We will disclose to the proper authority's information shared with us or activities we observe concerning abuse, neglect or harm to others or yourself.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others*;*
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

This Certificate may not be effective for information held in foreign countries.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

If information about you or your involvement in this research is placed in your medical record the information may no longer be protected under the Certificate. However, information in your medical records is protected in other ways.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?".

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form or as permitted or required by law. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- This authorization does not expire.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
    - To revoke your authorization, complete the withdrawal letter found in the Participant section of the Human Research Protection Office website at hrpo.wustl.edu.
        - **If you revoke your authorization:**
            - The research team may only use and share information already collected for the study.
            - Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons.
            - You will not be allowed to continue to participate in the study.

Can we contact you by email and/ or text?

We would like to contact you by email and/or text for the purposes listed below. Some of these messages may contain health information that identifies you.

- Patient education and appointment scheduling containing PHI.

Only the research team will have access to your email and/or text communications. We will only communicate in this method to send you the information listed above. If you have any questions, wish us to stop sending these messages or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email and/or text.

- Text messaging is not a secure communication method.
- There is always a risk that the message could be intercepted or sent to the wrong email address and/or phone number. To avoid this, we will send a test message to ensure we have the correct email address and/or telephone number.
- When using any computer, you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer or cell phone with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any messages sent or received on any electronic devices used for work or through a work server.

- If you lose your phone, others may be able to access the messages that we send.

Do you agree to allow us to send your health information via email?

_____ Yes **_____ No**
Initials **Initials**

Do you agree to allow us to send your health information via text?

_____ Yes **_____ No**
Initials **Initials**

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study or you may send in a withdrawal letter. A sample withdrawal letter can be found in the Participant section of the Human Research Protection Office website at hrpo.wustl.edu.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the last planned study visit, the researchers may ask you to complete some of the final steps such as lab work or imaging as applicable.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because they believe it is in your best interest or if you do not agree to changes that may be made in the study.

These are some reasons why the researchers may take you out of the study:

- Your involvement may be prematurely terminated if any of the following conditions apply:
- You no longer meet eligibility criteria
- You are lost to follow up
- You become pregnant
- The study stops
- The investigator's decision

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Patrick Olson, MD, PhD 314 454-0058. If you experience a research-related injury, please contact: Patrick Olson, MD, PhD 314 454-0058.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 08/12/26.

_____ _____
(Signature of Participant) (Date)

_____
(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)

_____
(Name of Person who Obtained Consent - printed)