Washington University in St. Louis

INFORMED CONSENT DOCUMENT

Project Title: WU 345: Immune responses to adjuvanted and non-adjuvanted seasonal influenza vaccines in the lymphoid tissues.

Principal Investigator: **Rachel Presti MD PhD**

Research Team Contact: **Rachel Presti MD PhD, Lisa Kessels RN BSN, Alem Haile, AJ Winingham , (314) 454-0058**

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. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

This is a research study conducted by **Rachel Presti PhD MD and Ali Ellebedy PhD** having to do with the body's responses to Influenza Virus Vaccine that is adjuvanted and non adjuvanted. We invite you to participate in this research study because you are a healthy volunteer and have not had a recent influenza vaccination. You should carefully consider the information in this consent document and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. It is your choice whether to participate or not.

If you agree and sign this consent, you will be volunteering to participate in the research study. The research team must give you a copy of this signed consent document.

1. **What is the research study about?**
   We are studying the bodies responses to Influenza Virus Vaccine that is adjuvanted and non adjuvanted

2. **Why should I consider participating?**

   It is possible that by measuring these differences, we can better understand how the body responds to flu vaccination and how long the immunity lasts. This is important because it could help make more effective flu vaccines in the future.

3. What will I be asked to do?

All of the procedures in this study are being done for research only.

- You will receive the standard licensed U.S. Food and Drug Administration approved killed influenza vaccine available for the current flu season named Afluria, which will be given by an injection (shot) into your upper right arm. You will receive the standard licensed U.S. Food and Drug Administration approved killed influenza vaccine available for the current flu season named Fluad, which will be given by an injection (shot) into your upper left arm.
- You will have 1 screening visit and 1-2 baseline visits then clinic visits at days 7, 14, 28, 60, 90, 120 and 180.
- We will draw your blood and do 8 ultrasound guided fine needle aspirations (FNA) of lymph tissue from under both of your arms.
- If you agree to take part in this study, your involvement will last for 6 months. Visits will range from 1-2 hours in length. There are up to 9-10 clinic visits altogether, including the screening and enrollment visits, and 8 follow-up visits.
- You may choose to stop participating and withdraw from the study at any time. If you withdraw from the study, the research team may continue to use the information already collected about you.

4. What are the risks?

- There are some risks to you if you agree to volunteer for this study. The most serious/most common risks are
- Blood Draws - The blood draw may cause bleeding, bruising, or pain.
- Flu Vaccines - Some of the common reactions to the killed flu vaccine are discomfort and bruising at the site of the shot, your arm may feel stiff or achy for a few hours, sore throat, headache, chills, and fatigue
- FNA: You may experience discomfort and bruising at the place where the FNA needle is inserted.

5. What are the benefits to me? To others?

There may be no direct benefit to you. However, a better understanding could help make more effective flu vaccines in the future.

6. Is there any financial cost to me?

There is no cost to you.

7. Will my information be confidential?

Yes, your identity will be kept confidential. Your information will be available only to those who are working on this study.

8. Who is the sponsor?

The study is sponsored by **National Institute of Allergy and Infectious Diseases (NIAID)**

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you are a healthy volunteer and have not had a recent influenza vaccination.

The purpose of this research study is to evaluate the immune response (reaction of the cells in your body) of the killed (inactivated) flu vaccine in healthy subjects. Influenza ("Flu") infection carries a risk of serious illness. The immune system is your body's defense against all sorts of infections and foreign invaders. When you get the flu vaccine, you are getting a dose of killed flu virus. Your immune system then builds protective reactions against the flu virus. Later, if you get exposed to the flu, these reactions help attack and kill the virus. You may not get sick at all, or you may have a much shorter or milder illness.

Doctors recommend an Influenza (Flu) vaccine for healthcare workers, people with certain conditions that increase their risk of complications from the flu (for example lung or heart disease), people with weakened immune systems, and people in close contact with people with weakened immune systems or other high risk conditions. The Centers for Disease Control and Prevention (CDC), the American College of Physicians, The American Academy of Family Physicians, and the American College of Obstetricians and Gynecologists all recommend that everyone older than 6 months of age receive an influenza vaccine annually unless there are medical contraindications. A contraindication is a medical condition that prevents the vaccine from being administered.

The "killed" flu vaccine is a vaccine made from an inactivated influenza virus that has been split apart and changed in such a way as to not to be able to grow at all in a human. The killed flu vaccine is given as an injection into your arm.

In this study we are using 2 influenza vaccines and studying how you immune system responds to vaccination. We assess this response by blood tests and most importantly from lymph node biopsies from the lymph node that directly drains the arm in which the vaccine in introduced. In this study we will assess the response of an adjuvanted vaccine called FLUAD and compare it to a non-adjuvanted vaccine called AFLURIA.

What is an adjuvanted vaccine?
An **adjuvant** is an ingredient used in some **vaccines** that helps create a stronger immune response in people receiving the **vaccine**. In other words, adjuvants help **vaccines** work better. In this study the adjuvant is MF59C.1 which is proprietary oil emulsion.

Why are adjuvanted vaccine used?
Adjuvanted vaccines are used in persons like elderly who have naturally diminished (by age) immune systems.

FLUAD and AFLURIA are approved by the U.S. Food and Drug Administration for vaccination to prevent influenza.

WHAT WILL HAPPEN DURING THIS STUDY?

There are up to 9-10 clinic visits altogether, including the screening and enrollment visits, and 8 follow-up visits.

Screening Visit
We will review and discuss the study and this informed consent form. You will be asked to read and sign this consent form, volunteering to participate in this study. We will ask you for your age and gender, we'll ask some questions about your health and what vaccines you may have had in the past to ensure that you are a healthy volunteer. We will write down what medicines you are taking. You will have your height and weight taken. You will have your blood pressure, pulse and temperature recorded. You will have blood work drawn to determine if you have normal blood counts and normal blood chemistries. For these tests, you will have about 1 tablespoon of blood drawn. If your lab tests are normal for this study, you will be enrolled at "Day 0," usually within a couple of weeks of the screening visit. You will come to the Infectious Disease Clinical Research Unit for most visits.

Pre entry- One procedure needs to occur prior to vaccination.

Ultrasound-Guided Fine Needle Aspiration (FNA)-Baseline
We will schedule a visit to the Interventional Radiology Suite where we will do the fine needle aspirations (FNA). In this study, fine needle aspiration is a type of biopsy procedure. In fine needle aspiration, a thin needle is inserted into an area located typically under your arm where lymph glands are located. Your lymph glands will be assessed and the lymph gland with the least amount of tissue will be sampled at this visit. It will be considered a baseline sample. We will try whenever possible to combine this visit with the screening visit.

You may receive an injection with a local anesthetic (a shot of painkiller) called lidocaine. The procedure takes about 1 hour.

It is possible that we are unable to locate lymph glands under at least one of your arms to evaluate during the study. Because studying this tissue is central to the aims of the study you will not be able to continue in the study.

Day 0 Vaccination Day
You will have your blood pressure, pulse and temperature recorded. Up to 60 ml (approximately 4 tablespoons) of blood will be drawn to test for baseline labs antibody levels. If you are a woman of childbearing potential, and it has been more than 14 days since you were last seen, you will have an additional urine pregnancy test to confirm that you are not pregnant before you are administered the flu vaccine. Although the flu vaccine is safe for pregnant women, this particular study does not allow the enrollment of pregnant women.

After all blood work is done, you will receive the standard licensed U.S. Food and Drug Administration approved killed influenza vaccine available for the current flu season named Afluria, which will be given by an injection (shot) into your upper right arm. You will receive the standard licensed U.S. Food

and Drug Administration approved killed influenza vaccine available for the current flu season named Fluad, which will be given by an injection (shot) into your upper left arm. When you receive the shots, there may be slight pain and burning during the injection and your arm may feel sore for a few hours after the shot. There is a small chance that the vaccine may cause a slight fever or a sense of feeling mildly ill.

Post Vaccination Visits (Days 7, 14, 28, 60, 90, 120 and 180)
At each post vaccination visit you will have your temperature and other vital signs recorded. At each visit, you will be asked about any changes in your health or changes in the medicines you are taking. At each visit about 8 tablespoons of blood will be collected.

FNA at Days 7, 14, 28, 60, 90, 120 and 180
In addition to the procedures described above on days 7, 14, 28, 60, 90, 120 and 180 we will plan to do fine needle aspiration (FNA) as well.

We will try whenever possible to combine FNA visits with the post vaccination visits. Occasionally scheduling issues may not allow this.

The table below illustrates the procedures of this study.

	Screening Visit (within 30 days of vaccination day	FNA Baseline Visit	Day 0 Vaccination Day within 0-14 days after BL FNA	Day 7 ± 2 days	Days 14 ± 2 days	Day 28 ± 7 days	*Day 60 ± 14 days	Day 90 ± 14 days	Day 120 ± 14 days	Day 180 ± 21 days
Visit Number	1	2	3	4	5	6	7	8	9	10
		These visits may be merged if convenient								
Informed consent	X									
History	X									
Update Med HX, Meds			X	X	X	X	X	X	X	X
Targeted Physical Exam	X									
Urine pregnancy test in WOCBP*	X		X							X
Vital Signs	X		X	X	X	X	X	X	X	X
FNA Evaluation		X								
Fine Needle Aspiration (FNA) BOTH ARMS		X		X	X	X	X	X	X	X
Vaccination FLUAD LEFT ARM-			X							
Vaccination AFLURIAD RIGHT ARM-			X							
Complete blood count, blood chemistries and cotting time.	X									
Research Lab 10 ml CPT			X	X	X	X	X	X	X	X
Blood volume	1 TBS		4TBS	8 TBS	8 TBS	8 TBS	8 TBS	8 TBS	8 TBS	8 TBS
Check for side effects	N/A	Solicited AEs	Solicited AEs	Solicited AEs	Solicited AEs	Solicited AEs	Solicited AEs	Solicited AEs	Solicited AEs	Solicited AEs

Overall, in the 6-month duration of the study, a total of about 3.08 cups of blood will be drawn from you.

The results of the study will not be disclosed to the doctors taking care of you. No decisions regarding your medical care will be based on the results obtained in this study.

Will you save my samples or research data to use in future research studies?

As part of this study, we are obtaining blood, tissue, and data from you. We would like to use this blood, tissue and data for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding immune responses to influenza 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. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data, blood, and tissue you give up any property rights you may have in the data and specimens.

This research will focus on gene expression analysis. In order to understand this concept you we need to define some terms. A **gene** is a small piece of genetic material written in a code and called DNA. Genes dictate what eye color a person has or their hair color. Each gene has within it a set of instructions for making molecules that organisms need to survive. Genes themselves cannot be used by an organism. Instead they must be turned into a gene product. **Gene expression** is the process by which the information contained within a gene becomes a useful product.

RNA is a copy of DNA. DNA is very important, since it holds the information needed for making new cells and maintaining life, so it never leaves the nucleus. RNA goes out to do work throughout the cell. It's also super important because without RNA our bodies would not be able to make proteins, which make up about 20% of our bodies.

We plan to determine the total RNA from your blood and count the levels of all genes or genes of interest. We then look at the connection between these counts and the functional quality (how well it works) of the immune response caused by the vaccination. This will allow us to understand which immune signaling pathways need to be targeted by vaccination in order to get the best immune responses.

We will share your blood, tissue, and data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories, only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your blood, tissue and data for future research you should contact the research team member identified at the top of this document. The blood, tissue, and data will no longer be used for research purposes. However, if some research with your blood, tissue, and data has already been completed, the information from that research may still be

used. Also, if the blood, tissue, and data have been shared with other researchers it might not be possible to withdraw the blood, tissue, and data to the extent it has been shared.

Please place your initials in the blank next to Yes or No for each of the questions below:

My blood, tissue, and data may be stored and used for future research as described above.

_____ Yes _____ No
Initials Initials

My blood and tissue may be stored and used for genetic testing as described above.

_____ Yes _____ No
Initials Initials

My blood, tissue, and data may be shared with other researchers and used by these researchers for the future research as described above.

_____ Yes _____ No
Initials Initials

Identifiers may be removed from your private information including data, tissue, and blood and used for future research or shared with others. If this occurs, we will not ask you for additional consent.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 20 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for 6 months. Visits will range from 1-2 hours in length. As detailed above there are up to 9-10 clinic visits altogether, including the screening and enrollment visits, and 8 follow-up visits.

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.

Some risks described in this consent document, if severe, may cause death.

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

- Blood Draws - The blood draw may cause bleeding, bruising, or pain. Some people become dizzy or feel faint. There is also a rare risk of infection.

- Flu Vaccines – (Afluria, Fluad) There are some common, expected reactions to the killed flu vaccine. Some of the common reactions to the killed flu vaccine are discomfort and bruising at the site of the shot, your arm may feel stiff or achy for a few hours, sore throat, headache, chills, and fatigue

- Lidocaine Injection (used to numb the skin): You may likely experience some temporary pain at the injection site, from the needle stick.

- FNA: You may experience discomfort and bruising at the place where the FNA needle is inserted.

The less common risks and discomforts expected in this study are:

- Flu Vaccines - A few people experience mild fever and body aches for 24 hours after getting the flu shot.

- FNA -hemorrhage, infection, injury to adjacent organs, adverse reaction to medications (lidocaine, chloroprep scrub) administered.

Rare but possible risks include:

- Flu Vaccines - Very rarely, people have a serious allergic reaction to the flu vaccine. You should not receive the flu shot if you are allergic to chicken, eggs, or Thimerosal (a preservative in contact lens solutions). Associated with the 1976 flu vaccine, a few subjects experienced temporary paralysis, a condition known as Guillain-Barre syndrome. However, this syndrome has not been seen with the more modern influenza vaccine preparations. You will receive a Center of Disease Control and Prevention “What You Need to Know” handout at the time of vaccination.

- Lidocaine Injection (used to numb the skin): You may rarely experience nausea, rash, and inflammation at the injection site. People who are allergic to lidocaine could have a serious reaction such as shortness of breath, wheezing, and low blood pressure. Very rarely, this could cause death. It is very important that if you know you have an allergy to lidocaine or any other type of local anesthetic, you do not participate in this study.

Women Capable of Becoming Pregnant

Flu vaccination is administered as standard of care for pregnant women. One study of influenza vaccination of approximately 2,000 pregnant women demonstrated no adverse fetal effects associated

with influenza vaccine. However, if you are a woman, to assure your safety and that of an unborn baby, if you become pregnant during the time this research is being conducted, you will not be able to participate in this voluntary research. If you do become pregnant during your participation in this study, you and your baby will be followed for monthly safety monitoring until your baby is born. You will be asked to sign a separate consent form should this occur.

If you are a woman 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.

Genetics

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 ARE THE BENEFITS OF THIS STUDY?

You may or may not benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because we may learn new things that will help others.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could choose to get the flu vaccine without being in this study or not get the flu vaccine at all. Your participation is completely voluntary and you have the right to refuse to be in this study.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

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

You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. A check will arrive in the mail at an address you provide 10-14 business days following each completed visit. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

For your time, inconvenience, travel and parking, you will be paid $50 for the FNA baseline evaluation visit and each visit. For each of the 8 planned FNA performed you will receive an additional $150. The total amount your time and travel will be compensated will be about $1,650 for completion of all scheduled study visits. If you are not able to complete all the study visits or procedures you will be paid for those you do complete.

WHO IS FUNDING THIS STUDY?

The National Institute of Allergy and Infectious Disease (NIAID) at the National Institutes of Health (NIH) is funding this research study. This means that Washington University is receiving payments from NIAID to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from NIAID for conducting this 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 (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 indicated 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 Institute of Allergy and Infectious Disease (NIAID) at the National Institutes of Health (NIH)
- 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 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
- 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 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 her will be able to see the list. The records will be kept in a locked, security controlled environment.

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.

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.

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.

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 http://hrpo.wustl.edu/participants/withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter.

- **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?

We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- Scheduling appointments, appointment providing reminders

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions 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.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- 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 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 email communications sent or received on any electronic devices used for work or through a work server.

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

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

Can we contact you by text?

We would like to contact you by text message for the purposes listed below.

- Scheduling appointments, appointment providing reminders

Only the research team will have access to your texting communications. We will only communicate by text to send you the information listed above. If you have any questions or need to contact us for an

urgent or emergent situation, please contact the research team member identified at the top of this document. Message and Data rates may apply. You may receive 11-12 messages over the 180 days of the study. You can text STOP or contact the research team member identified at the top of the consent form to opt-out of receiving these messages.

You should be aware that there are risks associated with allowing us to text you for the purposes of this study.

- There is always a risk that the text message could be intercepted or sent to the wrong telephone number. To avoid sending messages to the wrong number, the first text we send you will be a test message to ensure we have the correct telephone number.

Do you agree to allow us to send your appointment and phone call reminders 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 at https://hrpo.wustl.edu/participants/withdrawing-from-a-study/ under Withdrawing from a Research Study.

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 you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Rachel Presti, MD PhD (314) 454-0058 (24 hours). If you experience a research-related injury, please contact: Rachel Presti, 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, http://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: 12/06/22.

_____ _____
(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)