Vanderbilt University Medical Center Institutional Review Board
Informed Consent Document for Research

Version Date: August 12, 2019

Principal Investigator: Natasha Halasa, MD, MPH
Study Title: High vs. Standard Dose Flu Vaccine in Adult Stem Cell Transplant Recipients
Institution/Hospital: Vanderbilt University Medical Center

This informed consent applies to: Adults (18 years and older)

Name of participant:_____Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study. Anyone you authorize to receive your medical record will also get this note.

1. What is the purpose of this study?

You are being asked to take part in this research study because you had a Stem Cell Transplant (SCT) and you participated last year in this study. Flu can cause more severe infections in patients who have had a SCT since their immune system does not work as well. Also, people after SCT do not respond to vaccines as well as healthy adults, including flu vaccine. The purpose of this study is to look at the safety and immune response of Fluzone High Dose (HD)®, study vaccine, against flu in adults who had a SCT.

Immune response is the amount of antibodies in the blood. Antibodies help your body to fight off infection. The study vaccine is like a vaccine called Fluzone Quadrivalent®. Fluzone Quadrivalent® is a flu vaccine that is approved for use in adults in the United States. In this study, Fluzone Quadrivalent® is the standard influenza vaccine. Fluzone HD® is a higher dose influenza vaccine and is investigational. Investigational means the vaccine is not approved by the Food and Drug Administration (FDA) for use in adults less than 65 years of age. This vaccine is approved for adults over 65 years of age. Both Fluzone Quadrivalent® and Fluzone HD® are given as an injection (shot).

Fluzone Quadrivalent® protects against 4 flu types. The test vaccine (Fluzone HD®) is like Fluzone Quadrivalent®, it protects against 3 of the same flu types, but it has a higher dose of viral antigen (which helps fight infection). In this study, we are looking to see if this higher dose possibly provides better protection against flu like it does in older adults. Fluzone Quadrivalent® and Fluzone HD® do not contain any living flu virus. There is no chance for you to get the flu from either vaccine. Also, some experts recommend two doses of flu vaccine in SCT patients while others say one only. We will be testing two doses of either vaccine in this study. In addition, we will be comparing immune responses after receiving the vaccine across multiple years.
This study is being done at Vanderbilt and 3 other hospitals in the United States. Our goal this year is to enroll patients who participated in the study last flu season. .

2. What will happen and how long will you be in the study?

You will receive a total of 2 doses of vaccine, the first study visit you will have blood taken and then receive the first dose of the vaccine. There will be a second visit 4-6 weeks later to receive the second dose of the same vaccine, and blood will be taken from you before the vaccine. The third visit will be 4-6 weeks after the second dose of vaccine for blood. At each of these study visits, we will also swab your nose. The study staff will also contact you 1-3 days and 8-10 days after you get both vaccines. This is to see how you are doing. If you are receiving immunoglobulin (Ig) IVIG/SCIG on the same days as visit 1, 2 or 3 a second blood draw will occur after IVIG/SCIG. There are optional parts of the study, in which you can come 5-10 days (about one week) after each vaccine for a blood draw and nasal swab only and/or you come back about 6 months after the third visit for a blood draw only. If you decide to participate in the optional visits, you will be in the study for about 8 months. During influenza season, you will be contacted weekly to see if you have any influenza-like symptoms, and if you do, you will have a nose swab. On the days of the study visits, you will get a nose swab even if you do not have symptoms- this includes if you are coming for an optional or a supplemental visit. We will also monitor if you have proven flu until June 30th.

Principal Investigator: Natasha Halasa, MD, MPH
Study Title: High vs. Standard Dose Flu Vaccine in Adult Stem Cell Transplant Recipients
Institution/Hospital: Vanderbilt University Medical Center

Study Procedures	Visit 1 (day 0)	1-3 days and 8-10 days after visit 1	Optional 5-10 days after visit 1	Visit 2 (days 28-42)	1-3 days and 8-10 days after visit 2	Optional 5-10 days after visit 2	Visit 3 (28-42 days after visit 2)	Flu Season	Optional visit (180 days ±56 days after visit 3)	Until June 30th
Vaccine (HD-TIV vs SD QIV)	X			X						
Blood Draw	X*		X**	X*		X**	X*		X	
Telephone and/or electronic Communication		X			X			Weekly		
Nose swab without symptoms	X		X	X		X	X		X	
Nose Swab when sick	X	X	X	X	X	X	X	X	X	X
Proven clinical influenza illness review##	X	X	X	X	X	X	X	X	X	x

*a second blood draw will be obtained post-IVIG/SCIG if administered at this visit.
**optional visits: 5-10 days after each vaccine and if within the 8-10 visit window, a call is not needed
Proven clinical influenza illness is any breakthrough influenza illness confirmed by laboratory testing

If you have a severe allergy to eggs or egg protein, you must not take part in this study.

If you are able to join this study and are enrolled, you will either get two doses of the seasonal flu vaccine (Fluzone Quadrivalent®) or the higher dose of the seasonal flu vaccine (Fluzone HD®). **This year you will receive the same vaccine that you were given in the past, either high dose or standard dose.** This study is blinded, which means that you, the study doctor, and study staff will not know what vaccine you received.

Screening: Written consent will be obtained. This may be on or before visit 1.

VISIT 1: Screening & Vaccine Dose Visit (Day 0)
Before any study-related procedures are done, you will be asked to read and sign a consent form.
The following will be done:

- You will be asked some questions about your health.
- You will be asked if you are taking any medicines.
- A health care provider will do a targeted physical exam, including an oral temperature.
- You will be asked questions to decide if you can be in the study.
- If you are a woman of childbearing age, you may be asked to give a urine or blood sample for a pregnancy test. You will not be able to enter the study if the pregnancy test is positive or if you are breastfeeding.
- Blood (about 2-4 tablespoons) will be drawn with a needle to test for antibodies (which help the body fight off infection) to flu. Some of the blood may be taken for routine care, and some will be taken for research. The blood will be drawn through your central line if you have one. If not, it will be obtained by getting blood from the vein directly. A second blood draw may be needed if you are getting IVIG/SCIG.
- Once the study doctor has made sure it is OK for you to be vaccinated, you will be given either Fluzone Quadrivalent® or Fluzone HD®. The vaccine that you get will be decided by chance (like rolling dice), using a special computer program. A nurse will then give you the vaccine by injecting it with a needle into your arm. The study staff will watch you for at **least 15 minutes** after getting vaccine.
- A nose swab will be collected.

You will be given a thermometer. You will be asked to take your temperature once every day, at about the same

time every day (in the evening). You will be given a memory aid worksheet. This is where you should write down your temperature and any symptoms or illnesses that you have. Also, write down any new medicine taken and all extra doctor visits. This starts the day that you receive the study vaccine and every day for the next week.

Telephone and/or Electronic Communication (Days 1-3, Days 8-10 after first vaccine)
A team member will attempt to contact you. The following will be done:

- Ask about your health.
- Collect the information on the memory aid worksheet.
- Answer any questions you might have.

Save the memory aid worksheet. You may need to bring it in at the next visit if you have not already mailed it in. You can also take a picture of the memory aid and send it to the study team.

VISIT 2: Second Vaccine Dose Visit (Days 28 to 42) or 4-6 weeks
You will be asked to come back to clinic once between 28 to 42 days or 4-6 weeks after the first vaccine was given. You will then receive your second dose of the vaccine. This is what will be done:

- We will collect the memory aid worksheet if you have not already returned it.
- You will be asked about any changes in medicines that you are taking.
- You will be asked about your health. A health care provider will do a targeted physical exam, including an oral temperature.
- If you are a woman of childbearing age, you may be asked to give a urine or blood sample for a pregnancy test. You will not be able to enter the study if the pregnancy test is positive or if you are breastfeeding.
- Blood (about 2-4 tablespoons) will be drawn with a needle to test for antibodies (helps the body fight off infection) to flu. Some of the blood may be taken for routine care, and some will be taken for research. The blood will be drawn through your central line if you have one, if not it will be obtained by getting blood from the vein directly. A second blood draw may be needed if you are getting IVIG/SCIG.
- Once the study doctor has made sure it is OK for you to be vaccinated the second time, you will be given either Fluzone Quadrivalent® or Fluzone HD®. The vaccine that you get will be the same (Fluzone Quadrivalent® or Fluzone HD®) as you received the first time. A nurse will then give you the vaccine by injecting it with a needle into your arm. The study staff will watch you for at **least 15 minutes** after getting the vaccine.
- A nose swab will be collected.

You will be asked to take your temperature once every day, at about the same time every day (in the evening). You will be given a memory aid worksheet. This is where you should write down your temperature and any symptoms or illnesses that you have. Also, write down any new medicine taken and all extra doctor visits. This starts the day that you receive the study vaccine and every day for the next week.

Telephone and/or Electronic Communication (Day 1-3 and 8-10 after second vaccine)
A study team member will attempt to contact you. The following will be done:

- You will be asked about your health
- We will collect the information on the memory aid worksheet.
- We will answer any questions you might have.
  Save the memory aid worksheet. You may need to bring it in at the next visit if you have not already mailed it in. You can also take a picture of the memory aid and send it to the study team.

VISIT 3: Study Visit (28-42 days or 4-6 weeks after second vaccine
You will be asked to come back to the clinic once 4-6 weeks later after visit 2. This is what will be done

- We will collect the memory aid worksheet if you have not already returned it.

Principal Investigator: Natasha Halasa, MD, MPH
Study Title: High vs. Standard Dose Flu Vaccine in Adult Stem Cell Transplant Recipients
Institution/Hospital: Vanderbilt University Medical Center

- You will be asked about any changes in medicines that you are taking.
- You will be asked about your health.
- Blood (about 2-4 tablespoons) will be taken from your central line if you have one, if not it will be obtained by getting blood from the vein directly to test for antibodies to flu. Some of the blood may be taken for routine care and some will be taken for research. A second blood draw may be needed if you are getting IVIG/SCIG.
- A nose swab will be collected.
- If you will not be able to return for visit 3, study staff will arrange for a blood draw to be done locally and shipped to test for antibodies to flu. This will be a case by case approval. You will be called and asked about your health and any changes in medicines that you are taking. Also, you will be asked to collect a nose swab.

OPTIONAL VISIT 4 180 days ±56 days after visit 3.
You have the option to come back to the clinic six months after visit 3 for a blood draw and a nasal swab. Blood (about 2-4 tablespoons) will be taken from your central line if you have one, if not it will be obtained by getting blood from the vein directly to test for antibodies to flu.

OPTIONAL VISIT 5-10 days after each vaccine: You have the option of coming back 5-10 days (about one week) after each vaccine for a blood draw and a nasal swab. This is to test for how different cells of your immune system fight against flu. If seen during 8-10 days after your flu shot, we will not need to contact you again

Influenza (flu) Surveillance:
Once flu season has started and until it ends, we will attempt to contact you by telephone and/or electronic communication each week to know if you are having any flu-like symptoms. If you have fever $\geq$38.3°C (101°F) and/or two or more of the following: respiratory symptoms (runny nose, sinus congestion, post-nasal drip, shortness of breath, cough, wheezing, sputum production, sore throat, sneezing, watery eyes, ear pain, or hoarseness), or systemic symptoms (body aches or headache), you will be asked to collect a nose swab and mail it back to us or you will be seen by a doctor or study staff- if needed , and a nose swab will be collected. This will continue throughout the Flu season regardless if you finished the study visits. You may need to collect another swab for the same illness if it lasts longer than 14 days.

Nose Swabs when Sick:
Additionally, we will ask you to collect a nasal swab if you had the above-mentioned symptoms during your participation of the study (out of the flu season).

Proven Flu Disease:
We will ask you about any breakthrough clinical influenza illness during the study period and until June 30th even if you have completed study visits. We will also review your medical chart for proven flu disease.

3. Costs to you if you take part in this study:
If you agree to take part in this research study, you, and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Principal Investigator: Natasha Halasa, MD, MPH
Study Title: High vs. Standard Dose Flu Vaccine in Adult Stem Cell Transplant Recipients
Institution/Hospital: Vanderbilt University Medical Center

4. Side effects and risks that you can expect if you take part in this study:

Risks of the Fluzone Quadrivalent® vaccine:

Fluzone Quadrivalent® has been shown to be safe in both children and adults.

Common side effects include: Redness, swelling, or soreness at the site of the injection, which may last for a few days. Other reactions occasionally experienced include: fever, headache, muscle pain, fatigue, chills, nausea, vomiting, diarrhea, and malaise (a feeling of general discomfort).

Uncommon side effects include: With any vaccination, there is a very small possibility of an allergic reaction, such as a rash, swelling of the lips or face or throat, difficulty breathing, sudden drop in blood pressure, fast pulse, or sweating. If such a reaction occurs, it is usually almost immediately after the vaccination. This is why you will be required to remain in the clinic a minimum of 15 minutes after receiving the vaccine so that if this happens, immediate medical attention can be provided.

During the swine influenza vaccine campaign of 1976, about one per 100,000 vaccine recipients developed a paralytic illness called Guillain-Barré Syndrome (acute and rapidly progressive inflammation of nerves that causes loss of sensation and muscle weakness). This has not been seen consistently with other influenza vaccines. Most patients who develop Guillain-Barré Syndrome recover completely. Groups that recommend use of vaccines state that any risk you might have of developing Guillain-Barré Syndrome is less than that for a complication from influenza.

Other neurological disorders, such as encephalopathy (damage to cells in the central nervous system), optic neuritis/neuropathy (inflammation or damage of the optic nerve), partial facial paralysis, and brachial plexus neuropathy (problem with some of the nerves in the shoulder area) have been reported after influenza vaccinations. However, no cause and effect relationship has been established, and full recovery was almost always reported.

Risks of the High-Dose Fluzone® vaccine:

Fluzone HD® is investigational in adults less than 65 years old.
The same risks are reported for High-Dose Fluzone® as Fluzone Quadrivalent®, but there are some reports of increased local symptoms in persons 65 years of age and older compared to standard dose.
If you have side effects after getting vaccine, contact the study doctor. Also contact the site if you have changes in your health status.

Risks of Blood Draw:
Pain, redness, soreness, bruising, or infection may occur at the needle stick site. Rarely some people faint. However, we will use your line if you have one to limit these complications.

Risks of Pregnancy:
The risk of Fluzone Quadrivalent® or Fluzone HD® to an unborn baby is not known. If you become pregnant while you are in this study, you must tell your doctor at once. Also, women must not breastfeed while in this study. If you are a woman and are able to become pregnant, you will have a urine or blood test to make sure that you are not pregnant before you receive treatment in this study.

Nose swab:
Minor discomfort from nose swabs, and a rare event of bleeding from a nose swab. If this occurs, pressure will be applied to the nares to stop the bleeding.

5. Risks that are not known:
Because this treatment is investigational, meaning non-FDA approved, there may be risks that we do not know about at this time.

Principal Investigator: Natasha Halasa, MD, MPH
Study Title: High vs. Standard Dose Flu Vaccine in Adult Stem Cell Transplant Recipients
Institution/Hospital: Vanderbilt University Medical Center

6. Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt [or the Sponsor] to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt [or the Sponsor] to give you money for the injury.

7. Good effects that might result from this study:
a) The benefits to science and humankind that might result from this study:
The information learned in this study may be helpful in the further development of Fluzone HD® for the prevention of flu in SCT patients.
b) The benefits you might get from being in this study:
You will receive flu vaccine which may prevent you from getting the flu. There is no guarantee that you will benefit from this study.

8. Other treatments you could get if you decide not to be in this study:
You do not have to be in this study to get a flu vaccine. Flu vaccines are widely available and are recommended for SCT patients. However, you will not get the Fluzone HD® if you are under 65 years of age.

9. Payments for your time spent taking part in this study or expenses:
You will receive $50 for each blood draw, $25 for each vaccine, and $10 for each telephone and/or electronic communication after each vaccine if the memory aid was completed and returned (does not include flu season communication). During the influenza season, you will receive $5 for each week of completed communication- if on time.

We will pay $10 for each nose swab that is collected at home and returned to us during the study.

If you will be coming to the hospital for a study visit only, we will reimburse you for mileage distance. The standard mileage rate will be $0.58 per mile. This will be calculated depending on the mileage distance between your residence address and the study center.

We may ask you for your Social Security number and address before you are compensated for taking part in this study.

10. Reasons why the study doctor may take you out of this study:
The study doctor may decide that it is best for you to leave the study. If you are taken out of the study for any reason, you will be told why. If the study doctor takes you out of the study, you will be followed for safety, including the follow-up telephone and/or electronic communication, unless you withdraw consent for follow-up.

11. What will happen if you decide to stop being in this study?
Joining the study is voluntary (that is, you decide). If you join the study, you have the right to stop the study at any time and for any reason. You should tell your study doctor or nurse right away. Deciding to not be part of the study will not change your regular medical care in any way. If you decide to leave the study, we will ask to follow you for safety, including the follow-up telephone and/or electronic communication

12. Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of

Principal Investigator: Natasha Halasa, MD, MPH
Study Title: High vs. Standard Dose Flu Vaccine in Adult Stem Cell Transplant Recipients
Institution/Hospital: Vanderbilt University Medical Center
this study, please feel free to contact **Dr. Natasha Halasa at (615) 322-3346 or page Dr. Lora Thomas at (615) 835-8167. The study team can be contacted by texting (615) 200-8479 or emailing** pedsflustudy@vumc.org or hsctflustudy@gmail.com**.** The study team can also be reached by calling (**615) 875-9233** and having Dr. Halasa paged **at (615) 322-2250**.

For additional information about giving consent or your rights as a person in this study, please feel free to call the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Clinical Trials Registry:
A description of this clinical trial will be available on 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.

14. Confidentiality:
All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Information from this study, including your identifying information may be provided to the United States Food and Drug Administration (FDA), and other regulatory agencies.

Your identity and medical records and data related to this study will be kept confidential, except as required by the law, and except for inspections by Agencies that regulate experimental drug studies (including the FDA), auditors, members of Vanderbilt University Institutional Review Board (IRB), National Institutes of Health (NIH), and/or Sanofi Pasteur, the company that is providing the vaccine. By signing this consent form, you consent to the study doctor and his or her staff to collect and use personal data about you for the study ("study data"). This includes your date of birth, your sex, your ethnic origin, personal data on your physical or mental health or condition, and blood collected in the course of this study.

Your study data is protected by the use of a study subject code ("subject identification number"), which is a number specific to you. The study doctor is in control of the code key, which is needed to connect study data to you.

Vanderbilt may share information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Halasa, and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

This study may have support from the National Institutes of Health. If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

15. Authorization to Use/Disclose Protected Health Information
All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study

Principal Investigator: Natasha Halasa, MD, MPH
Study Title: High vs. Standard Dose Flu Vaccine in Adult Stem Cell Transplant Recipients
Institution/Hospital: Vanderbilt University Medical Center
team use and share your PHI as described below.

As part of the study, Dr. Natasha Halasa and her study team may share the results of your study and/or non-study linked laboratory tests as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the Food and Drug Administration (FDA), Vanderbilt University Institutional Review Board, NIH, Study Monitors, and/or Sanofi Pasteur, the company that supplies the vaccine, and insurance companies for billing purposes. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least seven years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time. Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Natasha Halasa in writing and let her know that you withdraw your consent. Her mailing address is VUMC, 1161 21st Ave. South, D-7235 MCN, Nashville, TN 37232. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

You have the right to see and copy the PHI we gather on you for as long as the study doctor or research site holds the data. To ensure the scientific quality of the research study, you will not be able to review some of your data until after the research study is finished

If you decide not to take part in this research study, it will not affect your treatment, payment, or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

_____
Adult's Printed Name

_____ _____
Adult's Signature Date

Consent obtained by:

_____ _____
Signature of Person & Title Date

_____
Printed Name of Person & Title

Leftover Blood Samples: After all study tests are done, we would like to keep any remaining blood to use in possible future research studies. These studies may test for antibodies against other bacteria or viruses. No human genetic tests will be performed on your samples. Your samples will be labeled only by a code—the study subject number –and will not be labeled with your name or initials. If these stored samples are tested in the future, no identifying information will be used in the reporting or publication of any results. Results from this future research would not be reported to you or your doctor. These coded specimens may be shared with other

Principal Investigator: Natasha Halasa, MD, MPH
Study Title: High vs. Standard Dose Flu Vaccine in Adult Stem Cell Transplant Recipients
Institution/Hospital: Vanderbilt University Medical Center
institutions and researchers.

You can decide if you want your samples to be used for future research. Your decision can be changed at any time by notifying the study doctors or study personnel in writing. Your decision about your leftover blood samples will not affect your participation in this study or other studies or your medical care.

Please check Yes or No to the questions below:
☐ Yes, you may store my unused coded (identified as described above) samples for an indefinite period of time for future research.

☐ Yes, you may store my unused samples for an indefinite period of time for future research as described above, but you must remove any information that could identify it as mine (labeling it only by study and dose group).

☐ No, you may not use my samples for other future research. Destroy my unused samples at the end of this study.

Optional visit 5-10 days after each vaccine, please check Yes or No to the questions below:
☐ Yes, I want to do the optional visits.
☐ No, I do not want to do the optional visits.

Optional visit 4 - **180 days ±56 days after visit 3, please check Yes or No to the questions below:**
☐ Yes, I want to do the optional visit.
☐ No, I do not want to do the optional visit.

Future Contact
We may want to contact you in the future to see if you would be interested to have your take part in future studies. This will not affect the status of this study.

Please check Yes or No to the questions below:
☐ Yes, you can contact me about future studies.
☐ No, I may not be contacted about future studies.

Principal Investigator: Natasha Halasa, MD, MPH
Study Title: High vs. Standard Dose Flu Vaccine in Adult Stem Cell Transplant Recipients
Institution/Hospital: Vanderbilt University Medical Center

Genetic Testing: The purpose of genetic testing is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment. You are being asked to allow you to give a sample of blood for genetic research related to this study. What we learn about you from this sample will not be put in your health record. Your test results will not be shared with you or your doctor. No one else (like a relative, boss, or insurance company) will be given your test results. Health insurance companies and group health plans may not request your genetic information that comes from this research. At any time, you may ask to have your sample destroyed. You should contact the study doctor or staff to have your sample destroyed and no longer used for this research study. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the sample, we will not be able to locate and destroy it. There will be no costs to you for any of the tests done on your sample.

Please check Yes or No to the questions below:

My blood sample may be used for this gene research.

☐ Yes ☐ No

My blood sample may be stored for future gene research for other health problems (such as cancer, heart disease, etc.).

☐ Yes ☐ No

Signature:_____ Date: _____