Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Natasha Halasa, MD, MPH Version Date: September 12, 2019
Study Title: Comparison of High vs. Standard Dose Flu Vaccine in Pediatric Stem Cell Transplant Recipients
Institution/Hospital: Vanderbilt University Medical Center

This informed consent applies to: Parent or Guardian

Name of participant:_____ Age: _____

This form has been developed for use in a research study that involves subjects who do not have the legal capacity to consent to their participation. The term "your child" is referring to the subject throughout this document.

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. Your child does not have to be in this research study. You can stop your child from 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 your child to be in this study. Your child's medical record will contain a note saying he or she is in a research study. Anyone you authorize to receive your child's medical record will also get this note.

1. What is the purpose of this study?
Your child is being asked to take part in this research study because he/she has had a Stem Cell Transplant (SCT) and participated in this study last year. Flu can cause more severe infections in patients who have had a SCT since their immune system doesn't work as well. Also, people after SCT do not respond to vaccines as well as healthy children, including the 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 children who had a SCT. Immune response is the amount of antibodies in the blood. Antibodies help your body to fight off germs. The study vaccine, Fluzone HD®, is similar to a vaccine called Fluzone Quadrivalent®. Fluzone Quadrivalent® is a flu vaccine that is approved for use in children and 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 children. This vaccine is approved for adults 65 years of age and older. Both Fluzone Quadrivalent® and Fluzone HD® are given as an injection (shot).

Fluzone Quadrivalent® protects against 4 flu strains. The test vaccine (Fluzone HD®) is like Fluzone Quadrivalent®, it protects against 3 of the same flu strains, but it has a higher dose of antigen (which helps fight germs). In this study, we are looking to see if this higher dose possibly provides better protection against flu like it does in older people. Fluzone Quadrivalent® and Fluzone HD® do not contain any living flu virus. There is no chance for your child getting 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 vaccines in this study. Your child will get either two doses of high dose or standard dose, the same as last year.
In addition to that, we are comparing immune responses after receiving the vaccine across multiple years. About 250 children from across the country have already participated in this study. This study is being done at Vanderbilt and 8 other children's hospitals. The goal this year is to enroll children who participated last year.

2. What will happen and how long will your child be in the study?
All children will receive a total of 2 doses of vaccine. At the first study visit your child will have blood taken from them 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 vaccine, and blood will be taken from them before the vaccine is given. The third visit will

be 4-6 weeks after the second dose of vaccine for blood. The study staff will also attempt to communicate with you (via telephone and/or electronic communication) 1-3 days and 8-10 days after your child get both vaccines. This is to see how your child is doing. If your child is receiving IVIG/SCIG on the same days as visit 1, 2, or 3, a second blood draw will occur after IVIG/SCIG. There is an optional part of the study, in which your child can come 5-10 days (about one week) after each vaccine and about 6 months after the second visit (visit 4) for a blood draw only. During influenza season, you will be contacted weekly to see if your child has any influenza-like symptoms, and if they do, they will have a nose swab. If your child's visits 1-4 occur during flu season, your child will get a nose swab even if your child does not have symptoms. Your child will be in the study for about 8 months depending on if they participate in the optional visit 4 and how long flu season is this year.

Study Procedures	**Visit 1 (day 0)**	**1-3 and 8-10 days later after visit 1**	**Optional visit 5-10 days later after visit 1**	**Visit 2 (days 28-42)**	**1-3 and 8-10 days later after visit 2**	**Optional visit 5-10 days later after visit 2**	**Visit 3 (28-42 days after visit 2)**	**Flu Season**	**Visit 4 (180 days ±42 days after visit 2 (Optional)**	**Day 0-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****		**X**	**X****		**Weekly**		
Nose swab during influenza season	**X**			**X**			**X**	**If symptomatic**	**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, telephone and/or electronic communication is not needed *** Proven clinical influenza illness is any breakthrough influenza illness confirmed by laboratory testing.										

If your child has a severe allergy to eggs or egg protein, he/she must not take part in this study. If your child is able to join this study and are enrolled, they will either get two doses of the seasonal flu vaccine (Fluzone Quadrivalent®) or the higher dose of the seasonal flu vaccine (Fluzone HD®). **Your child will receive the same vaccines that he/she was given last year, either two doses of high dose or standard dose.** This study is blinded, which means that you, your child, the study doctor, and study staff will not know what vaccine your child got.

VISIT 1: Screening & Vaccine Dose Visit (Day 0)
The screening visit will take place on the same day your child gets the study vaccine. Before any study-related procedures are done, you will be asked to read and sign a consent form. You may be asked to sign the consent at a visit prior to your child's screening visit. If your child is between 7 and 17 years old, he/she will also sign a separate assent form. The following will be done:

- You will be asked some questions about your child's health.
- You will be asked if your child is taking any medicines.
- A health care provider will do a targeted physical exam and oral temperature.
- You will be asked questions to decide if your child can be in the study.
- If your child is a girl, she may be asked to give a urine or blood sample for a pregnancy test if she has ever had a period in the past. She will not be able to enter the study if the pregnancy test is positive or if she is breastfeeding A small amount of blood (about 1-2 tablespoons) will be drawn with a needle to test for antibodies (helps the body fight off germs) 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 child's central line if they have one, if not it will be by getting blood from the vein directly. A second blood draw may be needed if your child is getting IVIG/SCIG.
- If flu season has started, a nose swab will be done to test for flu.
- Once the study doctor has made sure it is OK for your child to be vaccinated, he/she will be given either Fluzone Quadrivalent® or Fluzone HD®. The vaccine that he/she gets will be decided by chance (like rolling dice), using a special computer program. A nurse will then give your child the vaccine by injecting it with a needle into his or her arm. The study staff will watch your child for at **least 15 minutes** after getting vaccine.

You will be given a thermometer. You will be asked to take your child's 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 child's temperature and any symptoms or illnesses that he/she has. Also, write down any new medicine taken, and all extra doctor visits. This starts the day that he/she receives the study vaccine and every day for the next week.

Telephone and/or electronic communication (Days 1-3, Days 8-10)
A study team member will attempt to contact you by telephone and/or electronic communication. The following will be done:

- You will be asked about your child's health.
- We will collect the information on the memory aid worksheet.
- We will answer any questions you might have.

Save the memory aid, you may need to bring in the memory aid worksheet at the next visit or mail it in a provided addressed and stamped envelope after completion. You can also take a picture of the memory aid and send it to the 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. Your child will then receive their second dose of the vaccine. This is what will be done:

- We will collect the memory aid worksheet if you haven't already returned it.
- You will be asked about any changes in medicines that your child is taking.
- You will be asked about your child's health.
- A health care provider will do a targeted physical exam and oral temperature.
- If your child is a girl, she may be asked to give a urine or blood sample for a pregnancy test if she has ever had a period in the past. She will not be able to enter the study if the pregnancy test is positive or if she is breastfeeding.
- A small amount of blood (about 1-2 tablespoons) will be drawn with a needle to test for antibodies (helps the body fight off germs) 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 child's central line if they have one, if not it will be by getting blood from the vein directly. A second blood draw may be needed if your child is getting IVIG/SCIG.
- If flu season has started, a nose swab will be done to test for flu.
- Once the study doctor has made sure it is OK for your child to be vaccinated the second time, he/she will be given either Fluzone Quadrivalent® or Fluzone HD®. The vaccine that he/she gets will be the

same (Fluzone Quadrivalent® or Fluzone HD®) as they received the first time. A nurse will then give your child the vaccine by injecting it with a needle into his or her arm. The study staff will watch your child for at **least 15 minutes** after getting the vaccine.

You will be asked to take your child's 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 child's temperature and any symptoms or illnesses that he/she has. Also, write down any new medicine taken and all extra doctor visits. This starts the day that he/she receives 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 by phone, text, or email. The following will be done:

- You will be asked about your child's 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 or mail it in a provided addressed and stamped envelope after completion. You can also take a picture of the memory aid and send it to the 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 haven't already returned it.
- You will be asked about any changes in medicines that your child is taking.
- If flu season has started, a nose swab will be done to test for flu.
- You will be asked about your child's health. A small about of blood (about 1-2 tablespoons) will be taken from your child's central line if they have one, if not it will be by getting blood from the vein directly to test for new 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 your child is getting IVIG/SCIG.
- If your child 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. You will be called and asked about your child's health and any changes in medicines that he/she is taking. We will also ask you to swab your child's nose and mail the swab to the research team.

OPTIONAL VISIT 4: Study Visit (180 days ±42 days after visit 2)

- You will be asked to bring your child back to the clinic at about 6 months after visit 2…
- This is what will be done:
    - A small amount of blood (about 1-2 tablespoons) will be taken from your central line if you have one, if not it will be by getting blood from the vein directly to test for antibodies to flu.
    - If flu season has started, a nose swab will be done to test for flu.

OPTIONAL: Your child has the option of coming back 5-10 days (about one week) after each vaccine for a blood draw only. This is to test for how different cells of your child's immune system fights against flu.

Influenza (flu) Surveillance:
Once flu season has started and until it ends, we will attempt to contact you weekly by telephone, and/or electronic communication to know if your child is having any flu- like symptoms. If your child has a fever ≥38.3°C (101°F) and/or two 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 your child 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 your child finished the study visits.

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

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

3. Costs to you if your child takes 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 child's 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.

4. Side effects and risks that you can expect if your child takes 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 the vaccine is given 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 for people in your age group state that any risk you might have of developing Guillain-Barré Syndrome is less than that for a complication from illness with 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® is investigational in children. The same risks are reported for High-Dose Fluzone® as regular Fluzone Quadrivalent®, but there are some reports of increased local symptoms in persons 65 years of age and older compared to standard dose.

If your child has side effects after getting vaccine, contact the study doctor. Also contact the site if your child has changes in his/her 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 child's central line if they have one to limit these complications.

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

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.

6. Payment in case your child is 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 to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

7. Good effects that might result from this study:
a) The benefits to science and humankind that <u>might</u> 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. The benefits your child might get from being in this study:
Your child will receive flu vaccine, which may prevent them from getting the flu. There is no guarantee that your child will benefit from this study.

8. Other treatments your child could get if you decide not to be in this study:
Your child does not have to be in this study to get a flu vaccine. Flu vaccines are widely available and are recommended for SCT patients. However, your child will not get the Fluzone HD®.

9. Payments for you and your child's time spent taking part in this study or expenses:
You or your child will receive $50 for each blood draw, $25 for each vaccine, and $10 for each phone call 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 or your child will receive $5 for each week of completed communication.

We will pay $10 for each nose swab collected at home and returned to us. We may ask you for your or your child's Social Security number and address before you are compensated for taking part in this study. If your child 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 Vanderbilt University Medical Center.

10. Reasons why the study doctor may take your child out of this study:
The study doctor may decide that it is best for your child to leave the study. If he/she is taken out of the study for any reason, you will be told why. If the study doctor takes your child out of the study, he/she 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 your child from being in this study?
Joining the study is voluntary (that is, you decide). If your child joins 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 child's regular medical care in any way. If you/your child decide to leave the study, we will ask to follow him/her for safety, including the follow-up telephone calls.

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 your child has been hurt by being a part of this study, please feel free to contact **Dr. Natasha Halasa** at **(615) 322-3346** or contact the study team by texting at **(615) 200-8479** or by 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 child's 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 child's personal information in your child's research record confidential but total confidentiality cannot be guaranteed.

Information from this study, including your child's identifying information, the United States Food and Drug Administration (FDA) and other regulatory agencies.

Your child's 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 your child for the study ("study data"). This includes your child's date of birth, your child's sex, your child's ethnic origin, personal data on your child's physical or mental health or condition and blood collected in the course of this study.

Your child's study data are protected by the use of a study subject code ("subject identification number"), which is a number specific to your child. The study doctor is in control of the code key, which is needed to connect study data to your child. Vanderbilt may share your child's 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.

15. Certificate of Confidentiality:
To help us protect your child's privacy, we have a Certificate of Confidentiality from the National Institutes of Health (NIH). The researchers can use this Certificate to legally refuse to give information that may identify your child in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify your child.

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about your child or his/her involvement in this research. If you give your consent to release information to a medical care provider, an insurer, or other person to receive research information, then the researchers will not withhold that information.

The Certificate of Confidentiality *only* applies under US law. Therefore, all specimens and information sent to the US as part of this trial will be protected by the Certificate of Confidentiality.

16. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your child's protected health information (PHI) private. PHI is your child's health information that is, or has been gathered or kept by Vanderbilt as a result of your child's healthcare. This includes data gathered for research studies that can be traced back to your child. 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 child's PHI. If you decide to let your child be in this research study, you are also agreeing to let the study team use and share your child's 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, 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 child's PHI private. The study results will be kept in your child's 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 child's medical record will be kept for an unknown length of time. Any research data that has been put into your child's medical record will be kept for an unknown length of time. Unless told otherwise, your consent to use or share your child's 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 your child. 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 your child for as long as the study doctor or research site holds data. To ensure the scientific quality of the research study you will not be able to review some of your child's data until after the research study is finished. If you decide not to have your child take part in this research study, it will not affect your child's treatment, payment or enrollment in any health plans or affect your child's ability to get benefits. You will get a copy of this form after it is signed.

_____ _____

Parent/Legal Guardian Signature Date

_____

Printed Name of Parent/Legal Guardian

Consent obtained by:

_____ _____

Signature of Person & Title Date

_____

Printed Name of Person & Title

Optional Visits (5-10 days after visits 1 and 2)
Please check your choice:

☐ Yes, I would like my child to take part in the optional portion of the study and come back about one week after each vaccine for a blood draw to test how different cells in the immune system fight against flu.

☐ No, I do not want my child to take part in this optional portion of the study.

Optional Visit 180 days ±42 days after visit 2, Please check your choice:

☐ Yes, I would like my child to come back about 6 months after visit 2.

☐ No, I do not want my child to take part in this optional portion of the study.

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 child's samples. Your child's 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 institutions and researchers.

You can decide if you want your child's 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 child's samples will not affect their participation in this study or other studies or their medical care.

Please check your choice below:

☐ YES, you may store my child's unused coded (identified as described above) samples for an indefinite period of time for future research.

☐ YES, you may store my child's 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 theirs (labeling it only by study and dose group).

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

Future Contact

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

Please check your choice:

☐ YES, you can contact me about future studies for my child.

☐ NO, I may not be contacted about future studies.

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 your child to give a *sample of blood* for genetic research related to this study. What we learn about your child from this sample will not be put in your child's health record. Your child's 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 child's test results. Health insurance companies and group health plans may not request your child's genetic information that comes from this research.

At any time, you may ask to have your child's sample destroyed. You should contact the study doctor or staff to have your child's 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 child's sample. Also, if your child's 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 child's sample.

Please check Yes or No to the questions below:
My child's blood sample may be used for this gene research.

☐ Yes ☐ No

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

☐ Yes ☐ No

Signature:_____ Date: _____