Informed Consent to Participate in Research

Your Name: _____

Study Title: A Multi-Center, Randomized, Double Blind, Phase III Trial Evaluating Corticosteroids with Mycophenolate Mofetil vs. Corticosteroids with Placebo as Initial Systemic Treatment of Acute GVHD.

Protocol: 0802

Investigator: Javier Bolaños Meade, M.D.
Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins
1650 Orleans Street
Baltimore MD 21231
Phone: 410-614-6398.

Co-Investigator: Vincent T. Ho, M.D.
Dana Farber Cancer Institute
44 Binney Street
Boston MA 02115
Phone: 617-632-5938

Transplant Center Investigator: _____

Sponsor: The National Institutes of Health (NIH) gave financial support for this research study through the Blood and Marrow Transplant Clinical Trials Network (BMT CTN).

Introduction

You are invited to join a research study. This study will evaluate a GVHD treatment that includes the use of prednisone (a corticosteroid) and either: a placebo (sugar pill) or the study drug, mycophenolate mofetil (MMF). The placebo is not a treatment and will have no effect on your condition. The placebo or MMF will be randomly assigned to you.

If you decide to join the study, you will receive either steroids and MMF, or steroids and a placebo. If you choose not to join the study, you will receive standard treatment.

This Consent Form will tell you about the purpose of the research, its possible risks and benefits, other options available to you, and your rights as a participant in the study. Please take your time to make your decision.

Everyone who takes part in research at [insert facility name] should know that:

- Being in any research study is voluntary.
- You may or may not benefit from being in the study. Knowledge we gain from this study may benefit others.
- If you join the study, you can quit the study at any time.
- If you decide to quit the study, it will not affect your care at [insert name of facility or institution].
- Please ask the study staff questions about anything that you do not understand, or if you would like to have more information.
- You can ask questions now or any time during the study.
- Please take the time you need to talk about the study with your doctor, study staff, and your family and friends. It is your decision to be in the study. If you decide to join, please sign and date the end of the Consent Form.

You and your doctor will discuss other treatment choices if you do not want to participate in this study.

1. Background

This research study is sponsored by The National Institutes of Health (NIH) through the Blood and Marrow Transplant Clinical Trials Network (BMT CTN). The goal of this study is to find a better treatment for acute GVHD in people who have had an allogeneic blood stem cell transplant.

Acute GVHD is a medical condition that can become very serious. Acute GVHD is a common development after allogeneic stem cell transplant. It happens when the donor cells attack and damage your tissues after transplant. Acute GVHD often causes:

- Skin rashes
- Nausea (feeling sick to your stomach)
- Vomiting (throwing up)
- Abdominal pain
- Diarrhea
- Liver damage that can cause inflammation in the liver or jaundice (yellowing of the skin or eyes)

Patients with acute GVHD are at risk to develop chronic GVHD. Chronic GVHD may also cause damage to other organs. Acute and chronic GVHD may be bad enough to cause death.

Corticosteroid (or steroid) medications, such as prednisone, are the standard of care for early treatment of GVHD. However, less than half of patients will become free of acute GVHD when steroid treatment is used alone. Information from a BMT CTN study suggests that Mycophenolate mofetil or "MMF" in combination with standard steroid therapy may lower the risk of developing GVHD.

MMF is a drug that blocks the growth of the immune cells (T lymphocytes), which are believed to cause GVHD. MMF is approved by the U.S. Food and Drug Administration (FDA) to prevent rejection after organ transplant. MMF has been used for years as a treatment for GVHD that does not respond to standard corticosteroid therapy, or to prevent GVHD after allogeneic stem cell transplant.

2. Purpose

You are invited to join this research study because you have developed acute graft-versus-host disease (GVHD) and your doctor feels that treatment for the GVHD is necessary.

We will measure how the addition of MMF compares long-term to the standard treatment of steroids for acute GVHD. Specifically, we also want to know if MMF will:

- Reduce the symptoms and signs of acute GVHD, or
- Eliminate acute GVHD completely.

MMF will be compared to a placebo (sugar pill) to learn if it will reduce or eliminate your acute GVHD when added to the standard treatment of steroids.

We also want to collect extra blood samples and mouth swabs for future research on GVHD. You may take part in this additional study if you want to. You can still be part of the main study even if you do not want to donate extra blood samples.

3. Right to Ask Questions and/or Withdraw

You have the right to ask questions about the study at any time. If you have questions about your rights as a participant or you want to leave the study, please contact:
[insert contact info]

Being in this study is voluntary. You can choose to not be in this study, or leave this study at any time. If you choose to not take part or to leave this study, your regular medical care will not be affected in any way. This includes standard care for your acute GVHD.

If you decide to leave this study after taking the study treatment, or are asked to leave by your doctor for medical reasons, you will need to come back to the doctor's office for tests for your safety. Even if you withdraw from the study, the information collected from your participation will be included in the study evaluation, unless you specifically ask that it not be included.

Your study doctor and study staff will be available to answer any questions that you may have about your participation in, or your withdrawal from this study.

4. Procedures

Before you join the study, we will ask you about your medical history, and any medications you may be taking. It is important that you do not participate in the study if you suffer from an allergy to mycophenolate mofetil (MMF); or if you are pregnant, breastfeeding or are likely to become pregnant during the study.

Your doctor will do a number of tests to determine if you are able to join this study. These tests include:

- A physical exam that also measures the stage of your GVHD.
- Your ability to do regular daily activities (performance status).
- Routine blood tests to check your blood counts, how well your liver and kidneys work, and levels of GVHD prevention medications in your blood (if it applies to you).
- Pregnancy test (if it applies to you).

If you decide to join, we will ask you to sign this Consent Form, and you will get a copy of the signed form to keep.

There will be two study groups. One group will receive MMF and the other group will receive the placebo. Both groups will receive the standard treatment of steroids. About 372 patients will participate at several centers around the country. Your study participation will last about 12 months and you will be required to attend the clinic at least 8 times during the first 8 weeks of the study.

You may take the assigned placebo or MMF for up to 8 weeks. Once you stop taking the placebo or MMF, the study team will follow your health for up to 12 months after you first join the study.

Another part of the study will ask questions about your symptoms. This information will be collected at two times: enrollment on the study and approximately 56 days later. The survey has 19 questions and should take less than 5 minutes to complete. You may skip any questions you wish.

Randomization
We will randomly assign you to one of two study groups using a computer. This means that you will be put into a group by chance. It is like the flip of a coin or drawing names out of a hat. You will have an equal chance of being placed in either group.

You will not be told to which group you are assigned. Study staff at your visits will not know your group assignment either. We can find out which group you are assigned to if we ever need to know to protect your safety.

Additional Study Visits and Procedures
We will give you a placebo or MMF along with prednisone or methylprednisolone (steroids), which are standard treatment for acute GVHD. The placebo and MMF come in the form of pills. If you cannot take pills, the placebo or MMF can be given to you through your vein (IV infusion).

You will take your assigned drug three times each day for up to 8 weeks. We will watch you closely for:

- Signs of GVHD
- Changes in your blood counts, liver and kidney function
- Any side effects
- Signs of infection

Weekly Health Evaluations
We will evaluate your health every week for 8 weeks once you start taking your study drug. At your week 4 evaluation we will collect extra blood samples if you agreed to participate in the optional research sample portion of this study. Each health evaluation will include tests to evaluate your:

- GVHD stage
- Ability to do daily activities (performance status)
- Blood counts, liver and kidney function, and levels of GVHD prevention medications in your blood (if it applies to you)
- Development of any side effects or signs of infection

These tests and how often they are scheduled are standard care for patients with acute GVHD and would be done even if you were not part of this study.

Monthly Health Evaluations
Once you finish the 8 weeks of study treatment, we will evaluate you at approximately 3, 6 and 12 months after you first joined the study. During these visits, we will evaluate your:

- GVHD stage
- Ability to do daily activities (performance status)

- Routine blood tests including your blood counts, how well your liver and kidneys work, and levels of GVHD prevention medications in your blood (if it applies to you)

The evaluations at week 4 and week 8 must be done at the transplant center. Other exams and tests may be done at the transplant center or at a local doctor's office if your condition improves and it is closer to where you live, at the discretion of your transplant doctor.

These tests and how often they are scheduled are standard care for patients with acute GVHD and would be done even if you were not part of this study.

5. Alternative Treatments

Current available treatments which may be used to treat acute GVHD include:
- Corticosteroids without the study drug (standard treatment for GVHD)
- Participation in another clinical trial (if available, check with your doctor)

Every treatment option has benefits and risks. Your study doctor will discuss these options with you. If you decide not to participate in this research study, your medical care will not be affected in any way.

6. Risks and Discomforts

a.) Side Effects of Study Drugs
All drugs can have side effects, including the standard therapy for GVHD (steroids) and MMF being tested in this study. Your doctor will watch you carefully and will change your treatment if side effects develop. MMF used in addition to steroids for GVHD is an experimental treatment, but information has already been collected on its effects in people. We have a limited amount of information about children (pediatric patients) treated with MMF for GVHD.

Placebo:
The placebo will look and taste like MMF (mycophenolate mofetil) but it is not a drug. The placebo is not expected to have any side effects and it will have no effect on your condition.

Mycophenolate Mofetil (MMF):
MMF is a potent immunosuppressive drug that blocks the growth of the immune cells that can cause GVHD.

Risks and side effects related to MMF include those that are:

Common (more than 20% of patients)
- Infection
- Upset stomach, including nausea

Less common (less than 20% of patients)
- Low blood counts
- Vomiting
- Diarrhea

Rare but serious (less than 2-3% of patients)
- Serious injury to your gut (digestive tract), including bloody stools and vomit
- Secondary cancers, such as lymphoproliferative disease or lymphoma
- Serious infections of the brain
- Risk to a baby in pregnancy
- Progressive Multifocal Leukoencephalopathy (PML)

b.) Infections

Because GVHD is caused by an immune attack on your tissues from the transplanted donor cells, all treatments for GVHD include drugs to control (suppress) that immune attack. There is a higher risk of infection in patients with GVHD and any treatment for GVHD may also increase your risk of infection. Infections may be bad enough to cause death.

You will need to take several antibiotics to prevent infection. You will also be watched carefully for any infections while you are being treated for GVHD. Tell your doctors promptly if you get a fever, chills, cough or any other symptoms that might be a sign of an infection.

c.) Risks of Other Procedures Including Blood Draws

There are no major risks associated with drawing blood. Having your blood drawn can be uncomfortable and can sometimes cause a bruise. In rare cases, a blood draw can cause fainting. Only trained people will draw your blood.

d.) Reproductive Risks

MMF may cause injury or birth defects if it is taken during pregnancy. Because of this, it is important that you are not pregnant or breast-feeding and do not become pregnant during the course of the study.

If you are a woman and pregnancy is a possibility, you will need to take a pregnancy test before you start the study. You should discuss ways to not become pregnant while you are participating on the study. Unless you have been in menopause for at least 12 months in a row, pregnancy is a possibility.

MMF can make birth control pills less effective. You must either use abstinence or two non-hormone forms of birth control (such as a condom, diaphragm, or spermicide). You must continue to prevent pregnancy before and during your treatment with MMF, and for at least 6 weeks after your treatment ends.

Ask your doctor about abstinence or the most effective non-hormonal forms of birth control and which options are best for you. If you do become pregnant while you are in the study, you should tell your doctor right away. You will be removed from the study

drug and you will receive information on medical care, if you need it. You must not continue to take the study drug if you are pregnant.

e.) Unforeseen Risks
New risks might appear at any time during the study that are different from the risks listed in this Consent Form. We will promptly tell you of any new information that may affect your decision to participate.

f.) Other Treatments or Medications
Some medicines react with each other, and it is important that you tell the study doctor or staff about any other drugs, treatments, or medicines you are taking.

This includes non-prescription medications, vitamins and herbal treatments. It is also important that you tell the study staff about any changes to these medications during your participation in the study.

g.) Risks of completing the survey
Completion of the survey about your symptoms will not cause you any physical discomfort, although it is possible that you will find some of the questions or topics upsetting. If you do, there will be someone available to speak with you. They will be able to refer you to appropriate counselors or other support people.

7. Possible Benefits

Taking part in this study may or may not make your health better. While doctors hope that MMF in combination with steroids will be more useful against acute GVHD compared to the usual treatment, there is no proof of this yet. We do know that the information from this study will help doctors learn more about MMF in the treatment of acute GVHD. This information could help future allogeneic transplant patients

8. New Information Available During the Study

During this research study, new information about the study drug or the risks and benefits of the study may become known to the study doctors. If this happens, they will tell you about the new information.

The new information may mean that you can no longer participate in the study, or that you may not want to continue in the study. If this happens, the study doctor will stop your participation in the study and you will be offered all available care to suit your needs and medical conditions.

9. Privacy, Confidentiality and Use of Information

Your confidentiality is one of our main concerns. We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy.

Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Your study number is not related to your name, social security number or medical record number at [insert facility name].

Information about your transplant from your original medical records may be seen or sent to national and international transplant registries, including:

- The Center for International Blood and Marrow Transplant Research (CIBMTR)
- The National Marrow Donor Program (NMDP)
- The Food and Drug Administration (FDA)
- The National Institutes of Health (NIH), which include the National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute (NCI)
- Data and Coordinating Center of the Blood and Marrow Transplant Clinical Trials Network (BMT CTN), and
- Other authorized study organizations.

We will not identify you by name in any publications or reports coming from these organizations or groups.

10. Ending Your Participation

The study doctor or the study sponsor may stop the study at any time. We may ask you to leave the study if you do not follow directions or if you suffer from side-effects of the treatment. If you are asked to leave the study, the reasons will be discussed with you.

Possible reasons to end your participation in this study include:

- You do not meet the study requirements.
- You need a medical treatment not allowed in this study.
- The study doctor decides that it would be harmful to you to stay in the study.
- You are having serious side effects.
- You become pregnant.
- You cannot keep appointments or take study drugs as directed.
- The company making the study drug/placebo is no longer able to supply it.
- The study is stopped for any reason.

11. Physical Injury as a Result of Participation

It is important that you tell your study doctor or study staff if you feel that you have been hurt or injured because of taking part in this study. You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. This study will not pay for medical treatment. In case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

12. Compensation or Payment

You will not be paid for your participation in the research study. You will not get compensation or reimbursement for any extra expenses (travel, meals, etc.) you may have through your participation on this trial.

13. Costs & Reimbursements

Most of the visits for this research study are standard medical care for patients with GVHD and will be billed to your insurance company. You and/or your health plan/insurance company will need to pay for some or all of the costs of standard treatment in this study.

You or your insurance will not be charged for the study medication (MMF or placebo) or for the optional blood and DNA samples for research on this study. The study drug will be provided free of charge while you are participating in the study.

14. Ethical Review

The ethical aspects of this research study have been reviewed and approved by [name of IRB].

15. Further Information

If you need any information about this study, or if you have any problems while you are participating in this study you can contact the study doctor or his/her staff. They may be contacted at the telephone numbers listed here:

[Insert name and contact details].

16. Independent Contact

If you wish to speak to someone not directly involved in the study, or if you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact:

[Insert appropriate contact details]

Please note: This section of the informed Consent Form is about an additional research study that will be done with people who are taking part in the main study. You may take part in this additional study if you want to. You can still be a part of the main study even if you say 'no' to take part in this additional study.

Blood and DNA Samples for Research

We are asking your permission to collect and store extra blood and a DNA sample. These samples will be used for future research on GVHD tests and treatment. DNA is a molecule that contains a person's genetic information. We would collect a sample of your DNA by using a mouth swab.

DNA from your stored blood and DNA samples and your health information might be used in genome-wide association (GWA) studies for a future project either done or supported by the National Institutes of Health (NIH). Genome-wide association studies are a way for scientists to identify genes involved in human disease. This method searches the genome for small genetic changes that are more common in people with a particular disease than in people without the disease. Each study can look at hundreds of thousands of genetic changes at the same time. Researchers use data from this type of study to find genes that may add to a person's risk of developing a certain disease. If your coded genetic and clinical information is used in such a study, the researcher is required to add the DNA test results and non-identifying information into a public research database. This public database is called the NIH Genotype and Phenotype Database and it is managed by the National Center for Biotechnology Information (NCBI). The NCBI will never have any information that would identify you, or link you to your information or research samples.

A new federal law (2009), called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and employers of 15 or more persons to discriminate against you based on your genetic information. Health insurance companies and group health plans may not request your genetic information that we get from this research. This means that they must not use your genetic information when making decisions regarding insurability. Be aware that this new federal law will not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Procedures

- We will collect a sample of your DNA by using 4 mouth swabs on Day 0.
- We will collect blood samples at three different dates in the study: Pre-treatment baseline at Day 0, and then on Day 28 and Day 56 after treatment begins.
- The amount of blood collected from you is small – about 2 teaspoons (10-12mL) each time.
- These samples will be used for protocol-defined studies and may also be stored indefinitely for future research.

Withdrawal
If you agree to allow your blood and DNA samples to be used for research, you can change your mind at any time. If you change your mind, please contact [the Principal Investigator at your transplant center] in writing to state that you are withdrawing permission for your blood to be used for research. His/her mailing address is on the first page of this Consent Form. Any unused tissue will be destroyed if you withdraw your permission. **If you choose not to participate in this additional research there will be no change in your care**.

Benefits
You will not benefit directly from providing blood and DNA samples for this study.

Risks
There are no major risks associated with drawing blood. Having your blood drawn can be uncomfortable and can sometimes cause a bruise. In rare cases, it can cause fainting. Only trained people will draw your blood.

Confidentiality and Your Medical Information
The results of GVHD research done with your blood and DNA will not be part of your medical record and will not be shared with you.

If you agree to allow your blood and DNA samples to be used for research, they will be collected confidentially and your name will not be on the tubes. Only the study doctors or staff working with them will study the results from your blood and DNA samples.

Information gained from research on your blood and DNA may be used to develop of diagnostic procedures or new treatments for GVHD in the future. Your blood will not be sold to any person, institution, or company for financial gain or profit.

Making Your Choice
Please read each sentence below and think about your choice. After reading each sentence, make your selection by checking one of the boxes. If you have any questions, please talk to your doctor or nurse, or call our research review board at [IRB's phone number].

No matter what you decide to do, it will not affect your care.

- ❑ I agree to allow my blood and DNA to be used for future research.
- ❑ I do not agree to allow my blood and DNA to be used for future research.

_____ _____

Signature *Date*

Health Insurance Portability and Accountability Act 1 (HIPAA1) Authorization to use and disclose individual health information for research purposes

A. Purpose:
As a research participant, I authorize the Principal Investigators and the researcher's staff to use and disclose my individual health information for the purpose of conducting the research study:

A Multi-Center, Randomized, Double Blind, Phase III Trial Evaluating Corticosteroids with Mycophenolate Mofetil vs. Corticosteroids with Placebo as Initial Systemic Treatment of Acute GVHD.

B. Individual Health Information to be Used or Disclosed
My individual health information that may be used or disclosed to do this research includes:

- Demographic information (for example: date of birth, sex, weight)
- Medical history (for example: diagnosis, complications with prior treatment)
- Findings from physical exams
- Laboratory test results obtained at the time of work up and after treatment (for example: blood tests, biopsy results)

C. Parties Who May Disclose My Individual Health Information
The researcher and the researcher's staff may collect my individual health information from: (List hospitals, clinics or providers from which health care information can be requested).

D. Parties Who May Receive or Use My Individual Health Information
The individual health information disclosed by parties listed in item c and information disclosed by me during the course of the research may be received and used by the following parties:

- Principal Investigator and the researcher's staff
  Dr. Javier Bolaños Meade, Principal Investigator

  Dr. Vincent T. Ho, Co-Principal Investigator
- National Heart, Lung, and Blood Institute (NHLBI) and the National Cancer Institute (NCI), both of the National Institutes of Health (NIH)
- Study sponsors
  Blood and Marrow Transplant Clinical Trials Network (BMT CTN), data and coordinating center
- U.S. government agencies that are responsible for overseeing research such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP)

[1] HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information

- U.S. government agencies that are responsible for overseeing public health concerns such as the Centers for Disease Control (CDC) and federal, state and local health departments.

E. Right to Refuse to Sign this Authorization

I do not have to sign this Authorization. If I decide not to sign the Authorization, I will not be allowed to participate in this study or receive any treatment related to research that is provided through the study. My decision not to sign this authorization will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits.

F. Right to Revoke

I can change my mind and withdraw this authorization at any time by sending a written notice to the Principal Investigator to inform the researcher of my decision. If I withdraw this authorization, the researcher may only use and disclose the protected health information already collected for this research study. No further health information about me will be collected by or disclosed to the researcher for this study.

G. Potential for Re-disclosure

My individual health information disclosed under this authorization may be subject to re-disclosure outside the research study and no longer protected. Examples include potential disclosures for law enforcement purposes, mandated reporting or abuse or neglect, judicial proceedings, health oversight activities and public health measures.

H. This authorization does not have an expiration date.

TITLE: A Multi-Center, Randomized, Double Blind, Phase III Trial Evaluating Corticosteroids with Mycophenolate Mofetil vs. Corticosteroids with Placebo as Initial Systemic Treatment of Acute GVHD

I have read and understood this Consent Form. The nature and purpose of the research study has been explained to me. I understand that I will be given a copy of this signed Consent Form

_____ _____
Participant Name *Date*

_____ _____
Participant Signature *Date*

I certify that I have provided a verbal explanation of the details of the research study, including the procedures and risks. I believe the participant has understood the information provided.

_____ _____
Counseling Physician *Date*

_____ _____
Signature of Counseling Physician *Date*

Assent to Participate in Research

Study Title: A Multi-Center, Randomized, Double Blind, Phase III Trial Evaluating Corticosteroids with Mycophenolate Mofetil vs. Corticosteroids with Placebo as Initial Systemic Treatment of Acute GVHD

Protocol: 0802

A. Why am I here?

We are inviting you to join our study because you have acute graft-versus-host disease (GVHD). We want to learn if a new drug works better than the current drug we use to treat GHVD.

GVHD happens when your donor cells from your transplant attack parts of the body like your skin, stomach or liver. Both kids and adults can get GVHD. It can be a very serious problem for some people.

B. Why are you doing this study?

We are doing this study because we want to learn if a single drug or a combination of drugs work better to get rid of graft-versus-host disease (GVHD).

- Prednisone with a sugar pill (placebo) or
- Prednisone with MMF (mycophenate mofetil)

C. What will happen to me?

If you say you want to be in the study, we will ask you for several things:

- Permission to let us read your medical records and x-rays.
- Check-ups with the study doctors.
- Some blood from you (about 12 teaspoons). A very small needle will be used to get blood.
- We may also need a small piece (biopsy) of your skin, so we can study changes in your skin. If you agree to this, we will use numbing medicine before we take a small piece of skin with a special tool called a "punch."

Everyone in the study will take prednisone.

You will also take MMF or sugar pills (placebos). The doctors use a computer to choose which one. You will not know which drug you will take. The computer will keep it a secret from everyone, including the study doctors. If you get very sick, your study doctors can find out from the computer which drugs you take.

You will take the MMF or sugar pills 3 times a day for up to 8 weeks. If it is hard to swallow, the doctors can use a small needle to give it through your vein (IV) or your central line.

Once you finish taking the drugs, you will have about 4 more check-ups with either the study doctors or your regular doctor over the next 12 months.

We will watch you carefully for fevers, any sign of infection or other problems.

D. Will it hurt?

When you have your blood taken with a needle, it may feel like a pinch. It will hurt for a minute and sometimes the place where the needle went might be red and sore. You might get a little bruise where the blood was taken but it goes away in a few days.

If you have a skin biopsy, the numbing medicine burns when it goes in, but only for a few seconds. When the numbing medicine wears off, there may be some mild pain. It will leave a small scar.

E. Will the study help me?

We don't know if the study will help you or not. Your GVHD may stay the same, it may get better, or it may get worse.

F. What if I have questions?

You can ask any questions that you have about the study. If you forget to ask a question and think of it later, you can call me [insert office number]. You can also ask your question the next time you see me.

You can call the study office at any time to ask questions about the study.

G. Do I have to be in this study?

If you don't want to be in the study, you need to tell us and your parent or guardian. Your doctor will not be angry or upset if you don't want to join.

Whether you are in the study or not, you will still need to have treatment for your GVHD.

You can say yes now and change your mind at any time.

Please talk this over with your parent or guardian before you decide if you want to be in the study. We will also ask your parents to give their permission for you to join this study.

Use of Blood and DNA Samples
Some of your blood will be used to test for GVHD. Some of your blood and a sample of cells from inside your cheek (DNA) will be saved for future studies. To be in the study, you must agree to have your blood used for GVHD and other regular tests but you do not have to agree to have your blood or cheek cells (DNA) used in future studies.

Please check one of the boxes below to show how you want your blood and cheek cells (DNA) to be used.

- ❒ Yes, you may use my blood and cheek cell (DNA) samples for this study and future studies of GVHD.
- ❒ No, you may not use my blood and cheek cell (DNA) samples.

Writing your name on this page means that you agree to be in the study, and know what will happen to you. If you decide to quit the study, all you have to do is tell the person in charge.

You and your parent or guardian will get a copy of this form after you sign it.

_____ _____
Signature of Child *Date*

_____ _____
Signature of Researcher *Date*