Informed Consent to Participate in Research

A Randomized Double-Blind, Placebo-Controlled Trial of Soluble Tumor Necrosis Factor Receptor: Enbrel (Etanercept) for the Treatment of Acute Non-Infectious Pulmonary Dysfunction (Idiopathic Pneumonia Syndrome) Following Allogeneic Cell Transplantation

Your name:_____

Introduction
You are being invited to participate in a clinical trial. A clinical trial is a research study to answer specific medical questions. The information from this study may help future patients. This form tells you about the study. In addition, the study doctor (the person in charge of the research) will explain the study to you.

Please read this information and ask your study doctor about anything you do not understand. Please take your time to decide if you want to join this study. Some people find it helpful to have a family member or friend with them while learning about the study. You are being asked to join this study because you have a serious complication of transplantation affecting the lungs called Idiopathic Pneumonia Syndrome (IPS).

Before you decide whether or not to join the study, please read the information below. Feel free to ask questions. You do not have to participate in this research study - it is your choice. You and the medical staff at your transplant center will discuss other options before you make your decision.

It is important that you know:

- You will not be paid to be in this study.
- You or your insurance company will pay the bills for your medical treatment except that,
- You will not be charged for research tests or study medications.

Principal Investigator Contact Information at your Institution
Name/Title/Phone number/

Contact information for emergencies after hours or on weekends or holidays:
Name/Phone number/

Study Sponsor
The research in this study is paid for by the National Institutes of Health (NIH), which supports the Blood and Marrow Transplant Clinical Trials Network (BMT CTN). The BMT CTN will direct the research study. Some support will also be given by the Amgen Corporation, which makes the drug being tested in this study. All decisions about how the study is done are made independently by the BMT CTN and NIH.

Why is this study being done?
Pneumonia is a term that refers to the presence of fluid, congestion, or irritation or swelling in the lungs. Patients with pneumonia often have a cough and/or chest pain. They can be short of breath. Oxygen may be needed to help them breathe. In many cases, pneumonia is caused by germs such as viruses. However, sometimes patients develop symptoms of pneumonia but no germs are present. This is called Idiopathic Pneumonia Syndrome (IPS). IPS usually occurs within the first 180 days after transplant.

No one knows what causes IPS. No one knows why some patients get it and others do not. Recent studies have found that the lung fluid of patients with IPS contains certain chemicals that may directly damage the lung. One of these chemicals is called Tumor Necrosis Factor (TNF). Some recent tests suggest that TNF may be involved in causing lung damage.

Currently, there is no proven treatment for IPS. Patients may receive oxygen to help with breathing. They may receive medications (called diuretics) to remove fluid from their lungs. Patients often receive steroids to decrease some of the irritation and swelling in the lungs. Despite these treatments, many patients with IPS do not get better.

Etanercept is a drug approved by the Food and Drug Administration (FDA) for the treatment of rheumatoid arthritis (joint disease) and psoriasis (skin disease). We know that TNF is responsible for the damage caused to the joints or skin in patients with these diseases. Etanercept blocks the effects of TNF. Since we think that TNF may cause some of the lung damage in patients with IPS, it is possible that etanercept will help this disease too. In a previous small study of etanercept in patients with IPS, no serious side effects were seen. Some of the patients got better.

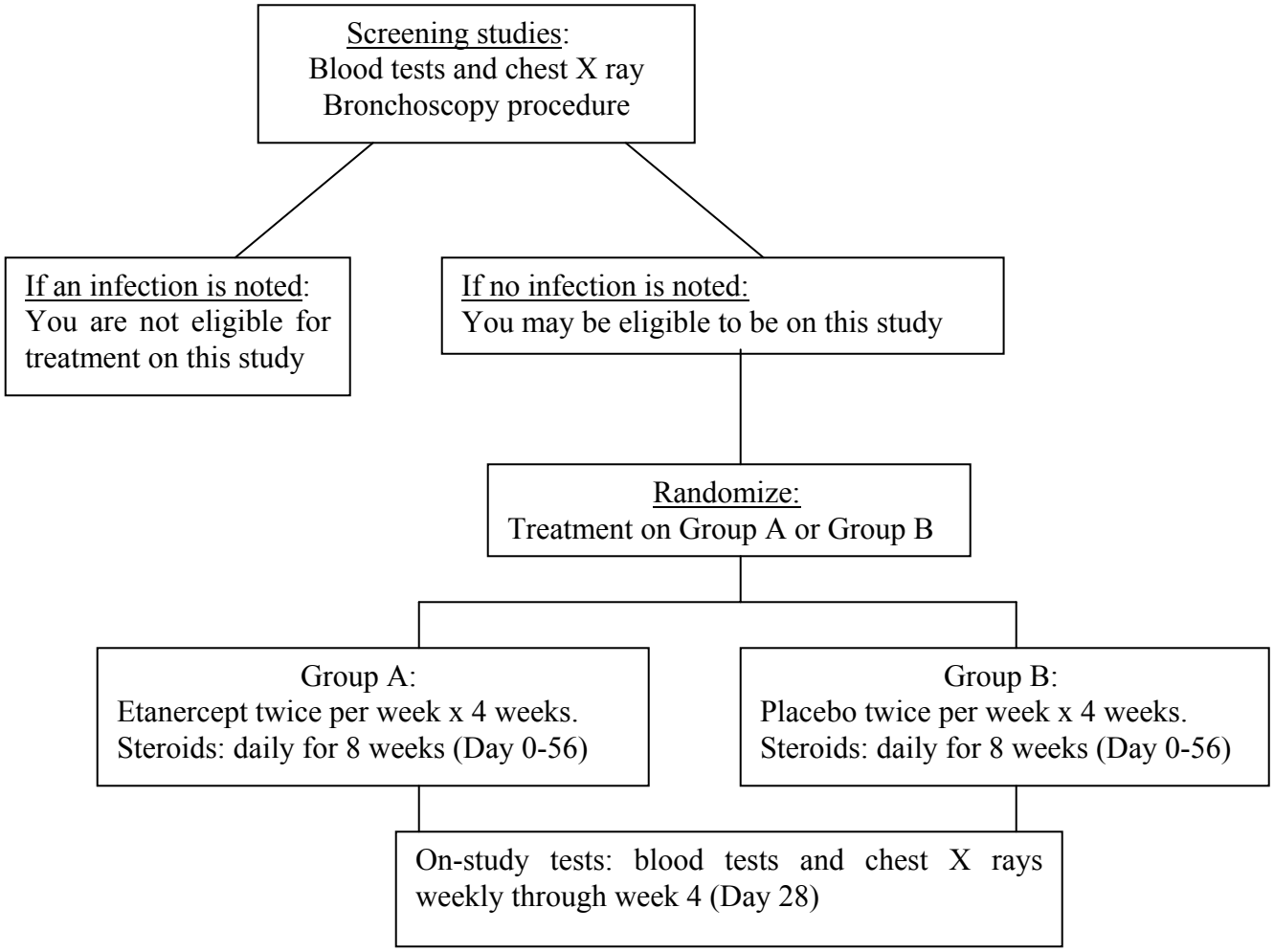
The purpose of this study is to find out whether adding etanercept to a commonly-used treatment for IPS (steroids) is more effective in treating IPS than steroids alone. Patients will receive either “etanercept and steroids” (Group A) or “placebo and steroids” (Group B). The placebo has no good or bad effect on IPS. Thus patients in Group B are actually receiving only steroids to treat IPS.

Steroids are the most common treatment for IPS.

Doctors want to know if giving etanercept plus steroids is better, the same or worse than giving steroids alone. The study will also see whether side effects result from adding etanercept to the commonly-used steroids. The study may help doctors make better treatment choices for future patients with IPS.

How many people will take part in the study?
A total of 60 patients will participate in this study. Thirty patients will be assigned to each group. This study will be done at more than 25 different medical centers in the United States, including [Center Name/Location].

What will happen if I take part in this research study?
The diagram below outlines the research study (the details follow the diagram). Start reading at the top and read down the list following the lines.



Screening studies:
You will need to have the following tests or procedures to find out if you are eligible for this study. We refer to these as "screening studies." These screening studies are often part of regular care, and may be done even if you do not join the study.

- *Chest X ray*
- *Blood tests*
- *Bronchoscopy*

Bronchoscopy: A bronchoscopy is a procedure performed by lung specialists. A small flexible tube is inserted into your nose (or mouth), and passed into your lungs. The tube has a light on one end that allows doctors to see into your lungs. The doctors will take out a sample of fluid from your lungs. This lung fluid will be tested for the presence of germs. If any germs are found, you can not be on this study but will receive treatment for the specific germs found. A portion of the fluid will also be tested for research purposes. The research will look for the presence of chemicals such as TNF.

During the bronchoscopy, you may or may not be put to sleep. In some cases, your doctor may place you on a breathing machine (called a mechanical ventilator). This will make sure you get enough oxygen during the procedure. At the end of the procedure, the breathing tube is usually removed. In some cases, however, the breathing machine may need to remain in place longer.

If you have had a bronchoscopy in the past 3 days, this procedure will not need to be repeated as long as no germs were found.

In some cases, your physician may choose not to do the bronchoscopy procedure. If your medical condition is such that a BAL is deemed "not possible to be performed" by your treating physician, then the "on study" BAL may be waived (not done). In this circumstance, you may enroll and still be randomized to study therapy without the BAL being undertaken.

Randomization:
If the results of tests and procedures show that you can be in the study, you will be "randomized" into one of the study groups described below. Randomization is done by a computer. Randomization puts you into a group by chance, much like flipping a coin. You will have an equal chance of being placed into either group. You will not be able to choose which group you are assigned. Neither you nor your doctors will know your group.

- If you are in Group A, you will receive treatment with etanercept plus steroids.
- If you are in Group B, you will receive treatment with steroids plus a placebo. The placebo will be a salt solution without medication.

You will not be able to tell the etanercept from the placebo, as both will look the same. Once you start treatment, you may not change to therapy in the other group while on this study.

Study Treatment:
The etanercept (or placebo) may begin within 24 hours after the bronchoscopy procedure. You will receive either etanercept or the placebo two times per week, for 4 weeks (see Table below).

There will be a total of 8 doses given. You will receive the first dose of etanercept (or placebo) as a 30-minute intravenous (IV) infusion. You will receive the second dose of etanercept (or placebo) as an injection under the skin (SQ) 3 days after the first dose. You will receive the remaining etanercept (or placebo) doses as injections under the skin approximately 3-4 days after the previous dose. The dosing plan is provided below.

GROUP A

Etanercept Dose	Time	How Administered
1	Day 0	IV
2	Day 3	SQ
3	Day 7	SQ
4	Day 10	SQ
5	Day 14	SQ
6	Day 17	SQ
7	Day 21	SQ
8	Day 24	SQ

GROUP B

Placebo Dose	Time	How Administered
1	Day 0	IV
2	Day 3	SQ
3	Day 7	SQ
4	Day 10	SQ
5	Day 14	SQ
6	Day 17	SQ
7	Day 21	SQ
8	Day 24	SQ

Key: IV, intravenous; SQ, injection under the skin

In addition to the etanercept (or placebo), you will also be given steroids (such as prednisone, Medrol, or Solumedrol). The steroids may be given to you by IV or by mouth. The dose of steroids you receive varies according to your weight. If you are getting better (requiring less oxygen to breathe) by Day 7 of treatment, the dose of steroids may be decreased.

If you continue to get better (requiring less oxygen to breathe), the steroid dosage will be decreased further over a 2-month period. In some cases, the steroids will be continued for a longer period of time (after 2 months).

Required tests while you are on the study:

Day:	Process:
Tests within 24 hours of study registration	Blood tests Chest X ray
Day 0	Bronchoscopy
Week 1	Blood tests Chest X ray
Week 2	Blood tests Chest X ray
Week 3	Blood tests Chest X ray
Week 4	Blood tests Chest X ray

Weekly blood tests will be obtained through week 4 (Day 28). Tests will include routine measurements of blood counts and electrolytes. Research tests will measure levels of certain chemicals called cytokines (including TNF) in the blood.

How long will I be in this study?
You will be treated on this study for 8 weeks. You will be given etanercept (Group A) or placebo (Group B) over 4 weeks, and steroids over about 8 weeks. Your participation on this study will last for one year as we follow how you are doing through regular visits with your transplant doctor. Follow-up for your transplant will last as long as you require care. However, we would like to keep track of your medical condition for the rest of your life. We will do this by contacting you and the doctor providing your regular medical care by phone or mail once a year. Keeping in touch with you and checking on your condition every year helps us know whether there are any unexpected long-term side effects of treatment. Many transplant centers include this type of long-term follow-up as part of their regular care.

Can I stop being in this study?
Yes. You can decide to stop at any time. Tell your doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

If you have any questions about your rights as a study subject, you may contact the Institutional Review Board (IRB) office at /number/.

Can the Principal Investigator withdraw me from this research study?
The study doctor may stop you from taking part in this study at any time if he/she:

- Believes it is in your best interest;

- If you do not follow the study rules; or,
- If the study is stopped.

You can be taken off the study (with or without your consent) for any of these reasons:

- If, after undergoing the bronchoscopy procedure, lab testing indicates that germs were present in your lungs. Your study treatment will be stopped. No further study treatment will be given.
- If you develop a severe side effect from the study treatment.
- You need treatment not allowed in this study.
- You do not follow directions that are important to being in the study.
- The study is cancelled.
- Other study-specific reasons, for example, if study doctors determine the study should be closed early because of side effects found in other patients.
- If your physician feels it is in your best interest to stop.

What side effect or risks can I expect from being in the study?
There are risks involved in this study. There may be side effects from the drugs or study procedures. The side effects **we know about now** are described below. Side effects can range from mild to severe. Some side effects may last only a short time (hours – days). Others may last longer.

Please talk with your doctor about possible side effects. If you want to read more about the drugs used in this study, please ask your doctor. We have grouped side effects according to how likely they are to happen:

Likely Side Effects	What it means: This type of side effect is expected to occur in more than 20% of patients. This means that 21 or more patients out of 100 might get this side effect.
Less Likely Side Effects	What it means: This type of side effect is expected to occur in 20% of patients or fewer. This means that 20 patients or fewer out of 100 might get this side effect.
Rare Side Effects	What it means: This type of side effect does not occur very often – in fewer than 2% of patients – but is serious when it occurs. This means that 1 or 2 patients (or fewer) out of 100 might get this side effect.

I. Risks related to the bronchoscopy procedure:

Bronchoscopy is a standard procedure for evaluating patients with pneumonia. You will be given a separate consent form to sign that explains the risks and discomforts.

II. Risk of steroids:

All patients on this trial will receive steroids. This is the most commonly used treatment for IPS. The following table shows expected side effects of steroids.

Likely *("Likely" refers to a side effect that is expected to occur in more than 20% of patients)*	• Difficulty sleeping • Increased susceptibility to infections • Weight gain, especially around the face/cheeks, shoulders, belly or legs • Muscle weakness • Pimples/acne • Increase in appetite • Increase in blood pressure • Increased levels of glucose (sugar) in the blood • Mood swings • Upset stomach (heartburn or gastritis)
Less Likely *("Less likely" refers to a side effect that is expected to occur in 20% or fewer patients)*	• Red face • Slow healing of cuts or other wounds • Slowed growth • Stretch marks and easy bruising of the skin • Abnormal electrolyte (salt) levels in the blood • Increased pressure in the eyes • Weakened bones (due to lower calcium levels in the bones) • Cataracts (thickening of the lens of the eye) • Headache • Dizziness • Infections
Rare, but Serious *(These possible risks have been reported in rare occurrences, typically < 2% of patients. They may be serious if they occur)*	• Joint damage, which can cause pain and loss of motion in that joint • Irritation of the pancreas (pancreatitis) • Irregular heart beat • Stomach and intestinal bleeding ulcers • Increased pressure in the brain, which can lead to difficulty seeing and headache • Bone fractures • Serious changes in mood, personality and/or severe depression

III. Risks related to etanercept: (this applies if you are assigned to Group A therapy)

Etanercept has been studied in both children and adults with a number of other conditions. These conditions include rheumatoid arthritis (a joint disease), psoriasis (a skin disorder), Crohn's disease, AIDS, heart failure, or serious infections. Infections, some serious, have been reported in these studies. Many infections occurred in patients who already had diseases that tended to weaken their body's ability to fight infection. In all cases, the occurrences of these side effects were rare. Also it is unclear whether or not etanercept was the cause. In patients with rheumatoid arthritis or psoriasis, the number of infections in patients treated with etanercept did not differ from the number in patients treated with a placebo. This included serious infections.

We cannot determine how etanercept may affect your risk of getting cancer. To date, the incidence of cancer in patients receiving etanercept has been similar to the risk in untreated people.

A small number of people receiving etanercept have formed antibodies *(proteins that attack foreign matter)* against etanercept. Although these antibodies do not appear to decrease the effect of the drug, it is a possibility that it may in some patients. The effects of a person developing antibodies to etanercept are not known. Your chances of developing antibodies are believed to be very low, < 5%.

Etanercept given by injection under the skin may cause local pain, bleeding, bruising, and rarely, an infection at the site of injection. A summary of the possible risks of etanercept is shown below:

Likely *("Likely" refers to a side effect that is expected to occur in more than 20% of patients)*	• Pain at the site of the injection
Less Likely *("Less likely" refers to a side effect that is expected to occur in 20% or fewer patients)*	• Increased risk of infections. Some of these infections may be serious or even life threatening • Irritation, itching, bruising, swelling or redness at the site of the etanercept injection • Hyper or hypothyroidism, where the thyroid gland produces too little or too much thyroid hormone • Belly pain, nausea and/or vomiting • High blood sugar levels • Blurred vision • Headache, or dizziness • Runny nose, sore throat

Rare, but Serious *(These possible risks have been reported in rare occurrences, typically < 2% of patients, but may be serious if it occurs. In most cases it is unclear whether or not etanercept was the cause.)*	• Severe allergic reactions during the infusion or injection • Severe rashes which can affect the skin and mouth, leading to pain, peeling of the skin and increased risk of infections • Headaches, seizures, strokes • Onset of multiple sclerosis or muscle weakness • Decreased blood counts, such as – A low number of white blood cells, which can make it easier to get infections – A low number of red blood cells, which can make you feel tired and weak – A low number of platelets, which causes you to bruise and bleed more easily • A relapse of one's cancer, or the development of a new cancer such as leukemia or lymphoma. Patients with Wegener's granulomatosis, a known immune system disorder, have had an increased risk of developing lymphoma. • Weakened heart muscle which may make you feel tired, weak, or short of breath • Recurrence of certain viral infections, such as the hepatitis B virus, which can lead to severe liver damage or liver failure • Recurrence of tuberculosis, if you have been previously infected with tuberculosis • Development of proteins (called antibodies) that react against your own body tissue. Collectively, these are called auto-immune reactions. They are often associated with rashes and fever. • Blood clots, or bleeding problems

There may be other, as yet unknown, side effects of etanercept.

IV. Reproductive risks: The effects of etanercept on your ability to get pregnant is not known. Its risks to an unconceived, unborn or newborn child are also unknown. Because the drugs in this study may affect an unborn baby, you should not become pregnant or father a baby while on this study. You should not nurse a baby while on this study. Women or men of child-bearing potential are not allowed to be in the study unless they use birth control (which may include abstinence).

V. Risks related to the placebo: (this applies if you are assigned to Group B therapy)
The treatment with placebo is anticipated to have few side effects. Pain at the site of the injections of the placebo may be noted in > 20% of patients receiving the placebo injections.

Are there benefits to taking part in the study?
Being in this study may or may not lead to any direct benefit for you. We also hope that information gathered in this study will help future patients with IPS.

What other choices do I have if I do not take part in this study?
If you do not take part in this study, you will be followed and treated according to the usual practice at your transplant center. This may include, for example:

- Bronchoscopy.
- Supportive care such as oxygen, or medications to remove fluid from your lungs.
- Steroid medications to treat IPS.
- Etanercept to treat IPS (this etanercept is the same as the study drug, but it would be given to you not as part of this study).

You should know about your treatment choices before you decide if you will take part in this study.

What are the costs of taking part in this study?
You or your insurance company will pay for all standard care relating to your transplant and IPS. This includes (but not limited to) routine blood tests, chest X-rays, and bronchoscopy procedures.

You will not be billed for tests that are only done for research purposes. These include the cost of the etanercept or placebo, and the cost of laboratory studies to measure chemicals called cytokines, such as TNF.

You will not be paid to be in this study.

Amgen, the company that makes etanercept, is providing funds for some of the costs of this study. However, Amgen did not plan or design this clinical trial. Amgen will also not have a part in analyzing the results of this study.

Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out if they will pay.

For questions about your costs, financial responsibilities, and/or medical insurance coverage for your transplant and this study, please contact /Center/ Financial Counselor at /Number/.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

What if I am injured as a result of being in this study?
In the event that this research activity results in an injury, treatment will be available. This treatment includes first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed to your insurance company. If you think you have suffered a research related injury, let the study doctors know right away. Unexpected side effects or accidents might result in your getting sicker than anticipated. All available medical care will be provided to you, but you and your insurance company are responsible for the costs of all such care.

What are my rights if I take part in this study?
Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you. You will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information that may effect your health or your willingness to stay in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Will my medical information be kept private?
Your participation in this research study will be kept private and confidential. All your medical and demographic (such as race and ethnicity, gender and household income) information will be kept private and confidential. *(Name of Transplant Center)* and the organizations listed below will not disclose your participation by any means of communication to any person or organization, except by your written request, or permission, or unless required by federal, state or local laws, or regulatory agencies.

Individuals authorized by the organizations below will have access to your research and medical information. They may use this information for inspections or audits to study the outcomes of your treatment. In agreeing to participate, you consent to such inspections and to the copying of parts of your records, if required by these organizations.

<u>Organizations with access to your research and medical records:</u>

- /Institution/
- The National Institutes of Health (NIH)
- The National Heart, Lung, and Blood Institute (NHLBI)
- The National Cancer Institute (NCI)

- Office of Human Research Protection (OHRP)
- The Food and Drug Administration (FDA)
- Institutional Review Boards (IRBs) responsible for this study
- Data and Safety Monitoring Board (DSMB), not part of /Institution/
- Blood and Marrow Transplant Clinical Trials Network (BMT CTN), including the Center for International Blood and Marrow Transplant Research (CIBMTR), the National Marrow Donor Program (NMDP) and the EMMES Corporation who are coordinating the studies of the BMT CTN
- Representatives of Amgen, Inc. (drug supplier for the etanercept used in this study)
- Study investigators

Scientific and medical findings resulting from a study may be presented at meetings. They may be published so that the information can be useful to others. You will not be identified in these presentations and publications.

Information related to or resulting from your transplant will be reported to the CIBMTR. The CIBMTR is a voluntary organization of basic and clinical scientists working together to gather results of stem cell and marrow transplants. This information is used to guide clinical decisions and identify ways to improve transplant outcomes. Scientific data or medical information (not identifiable with you) that could be useful to others may be presented at meetings and/or published in medical journals.

For questions about access to your medical records, please contact /name/ at /number/.

HIPAA[1] authorization to use and disclose individual health information for research purposes

a. Purpose: As a research participant, I authorize the Principal Investigator and the researcher's staff to use and disclose my individual health information for the purpose of conducting the research study entitled *A Randomized Double-Blind, Placebo-Controlled Trial of Soluble Tumor Necrosis Factor Receptor: Enbrel (Etanercept) for the Treatment of Acute Non-Infectious Pulmonary Dysfunction (Idiopathic Pneumonia Syndrome) Following Allogeneic Cell Transplantation.*

b. Individual Health Information to be Used or Disclosed: My individual health information that may be used or disclosed to conduct this research includes: demographic information (e.g., age, date of birth, sex, weight), medical history (e.g., diagnosis, complications with prior

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

treatment), physical examination findings, and laboratory test results obtained at the time of work up and after transplantation (e.g., blood tests, biopsy results).

c. Parties Who May Disclose My Individual Health Information: The researcher and the researcher's staff may obtain my individual health information from:

(list hospitals, clinics or providers from which health care information can be requested)

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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 at the University of Michigan
- Staff/laboratories identified in the protocol for the evaluation of other laboratory samples
- 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), including the Center for International Blood and Marrow Transplant Research (CIBMTR), the National Marrow Donor Program (NMDP) and the EMMES Corporation who are coordinating the studies of the BMT CTN
- 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)
- 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.
- Others:

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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 research-related treatment that is provided through the study. However, 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.

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Is there an expiration date for keeping my records?
Study records will be kept indefinitely by the transplant center for re-analysis and follow-up. If you have questions about the keeping of your research records or access to your files, please call /name/ at /number/.

Will researchers benefit from me being in this research study?
Your doctors have no money invested and will not get any financial gain from this study. Presenting research results may help the career of a doctor. Therefore, the doctors running this research study may benefit when the results are presented at scientific meetings or in the scientific press.

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BLOOD AND LUNG FLUID FOR FUTURE RESEARCH:

Please note: This section is about future research studies. These studies will be done using blood and lung fluid samples. You may give samples for these future research studies if you want to. You can still be a part of the main study even if you say 'no' to allowing these samples to be used for future research studies. Please mark your choice at the end of this section.

The study investigators ask your permission to store and use any remaining blood or lung fluid for future research. If your blood/lung fluid has already been collected, any remaining blood/lung fluid will be used for research, if you agree. These future studies may help researchers learn more about IPS and your response to treatment. Researchers may also perform genetic studies to determine whether there are correlations among your genetic make-up, the risk of developing IPS, and your response to treatment. This new research will be unlinked to your private personal information or other medical history. The doctors involved in running this study will not give other researchers your name, address, phone number, or any other information that will let the researchers identify you. Data generated from your blood/lung fluid will be entirely investigational. Reports about research done with your blood/lung fluid will not be given to you or your doctor. These reports will not be put in your health record.

Your blood/lung fluid may be distributed to the researchers in the BMT CTN and other qualified researchers interested in IPS or other transplant-related complications. As noted above, the researchers will be given these samples without any potentially identifying information. Information gained from research on your blood/lung fluid may be used for the development of diagnostic procedures or new treatments for lung complications after transplant. Your blood/lung fluid will not be sold to any person, institution, or company for financial gain or profit. Moreover, neither you nor your heirs will gain financially from discoveries made using the information and/or specimens that you provide.

In some cases, you may have already given consent to your treating institution or the National Marrow Donor Program (if you were the recipient of stem cells from an unrelated donor) for the collection of blood samples prior to your bone marrow transplant. If this has occurred, your treating institution (or the NMDP) will also be requested to, when possible, supply a portion of these samples for research purposes. In addition, you will be asked to provide a tissue sample that could be collected by rubbing a cotton swab on the inside part of your cheek.

Things to Think About: The choice to let us use these samples for future research is up to you. No matter what you decide to do, it will not affect your care.

If you decide now that your blood/lung fluid can be kept for research, you can change your mind at any time. If you change your mind, we ask that you tell [the study Principal Investigator] in writing; his/her mailing address is on the first page of this form. Tell your doctor that you do not want us to use your blood or lung fluid. Then any blood/lung fluid that remains will no longer be used for research.

Benefits: You may not get any direct benefit for providing blood/lung fluids for this study, but the research performed with these samples may help us learn more about what causes IPS and other complications after transplantation, and how to prevent and/or treat them.

Risks: The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private and secure. The chance that this information will be given to someone else is very small.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Making Your Choice: Please read each sentence below and think about your choice. After reading each sentence, please indicate your choice below. If you have any questions, please talk to your doctor or nurse, or call our research review board at _____.

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

- ❑ I agree to allow my blood, lung fluid and cheek swab used to be used for future research.

- ❑ I do not agree to allow my blood, lung fluid and cheek swab to be used for future research.

_____ _____
Signature *Date*

Who can I contact if I have questions or problems?
If you think you have suffered an injury as a result of this study, or have any other problems, you may contact (INSERT CONTACT INFORMATION). If it is after normal business hours or a weekend, you may contact (INSERT CONTACT INFORMATION).

If you have any questions about this study, you may contact the study Principal Investigator listed on the first page of this form.

If you have questions about your rights as a research participant, you may contact (INSERT CONTACT INFORMATION).

Consent for Treatment:

I have been informed about this study's purpose, procedures, possible benefits and risks. I have been given a chance to ask questions and have had them answered to my satisfaction. I understand that I can ask more questions at any time.

I voluntarily agree to participate in this study.

By signing this consent form, I have not given up any of the legal rights which I otherwise would have as a subject in a research study.

_____ _____
Signature of Subject *Date*

_____
Print Name of Subject

_____
Signature of Legally Authorized Representative *Date*

Certification of Counseling Healthcare Professional

I certify that the nature and purpose, the potential benefits, and possible risks associated with participation in this study have been explained to the above individual and that any questions about this information have been answered.

_____ _____
Counseling Healthcare Professional *Date*

Use of an Interpreter: Complete if the subject is not fluent in English and an interpreter was used to obtain consent:

Print name of interpreter: _____ Date: _____

Signature of interpreter: _____

An oral translation of this document was administered to the donor in _____ (state language) by an individual proficient in English and _____ (state language). See the attached short form addendum for documentation.