The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	**Reduce Intensity Conditioning (RIC) Allogeneic Hematopoietic Stem Cell Transplantation (allo HSCT) for Patients with Relapsed Multiple Myeloma: A pilot study**
Principal Investigator:	**Srinivas Devarakonda, MD**
Sponsor:	**The Ohio State University**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.

The Sponsor of this study is The Ohio State University.

Purpose: The purpose of this research is to develop a platform for Allogeneic Hematopoietic Stem Cell Transplantation (allo HSCT) in relapsed multiple myeloma patients, with the idea

of maximizing anti-myeloma effect and minimizing complications following the stem cell transplant. The study will help doctors decide whether this treatment regimen is effective in preventing graft-versus-host disease (GVHD), for future transplant patients.

Procedures: Before the transplant, you will have testing to see if you are a suitable candidate for this study and transplantation. You will receive the conditioning regimen of fludarabine and melphalan to prepare your body for transplant. The treatment with cyclophosphamide, tacrolimus and mycophenolate mofetil will start after you receive the donor's stem cells, and the treatment with daratumumab will follow for post-allo-HSCT maintenance.

Risks: Most of the risks you may experience are from the medications you will receive and the transplant. More details can be found in the following consent.

Benefits: Information from this study may help doctors learn more about medications used to prevent GVHD for future transplant patients.

Duration: You will be in the study for 2 year after your transplant.

All of the anti-cancer treatment drugs are approved for multiple myeloma, and the drugs we will be using to prevent GVHD are commonly used drugs for many types of transplant, including blood and marrow transplants. All of the drugs in this study are commonly used for patients with relapsed multiple myeloma or who receive a stem cell transplant from a donor, but these treatments together - a reduced intensity stem cell transplant, medications to help prevent GVHD, and maintenance therapy with daratumumab - have not previously been tested for relapsed multiple myeloma.
Fludarabine is chemotherapeutic drug given intravenously (an injection into your vein). It belongs to a class of medications called purine analogs, and it works by slowing or stopping the growth of cancer cells in your body.

Melphalan and Cyclophosphamide are chemotherapy drugs commonly used in treating multiple myeloma, and are given intravenously. They belong to the class of drugs known as alkylating agents, and work by causing the death of both dividing and non-dividing tumor cells.

Tacrolimus (given orally or intravenously if needed) and Mycophenolate mofetil (given orally or intravenously) are immunosuppressive drugs whose main use is after organ transplant to reduce the activity of the patient's immune system and so the risk of organ rejection.

Daratumumab is a monoclonal antibody given intravenously that attaches to multiple myeloma cells and tells the immune system to attack them. This action by the body can decrease multiple myeloma cells growth and therefore can prevent tumor growth.

Allogeneic stem cell transplant is not considered a standard of care in multiple myeloma. It is recommended that it is done in a clinical trial setting. There may be alternative, approved therapies for your relapse/refractory myeloma.

The procedures and treatment plan are outlined in greater detail below. Your participation in this study is completely voluntary.

1. Why is this study being done?

You have been invited to participate in this research study, because you have relapsed multiple myeloma that is resistant to chemotherapy, with or without prior autologous HSCT, and with a partial response or better prior to allo-transplantation.

Your study doctor will explain the clinical study to you. This research study includes only patients who choose to take part. Your participation is entirely voluntary. To allow you to make an informed decision as to whether or not you want to take part in this research study, this document describes the purpose of the study, your rights and obligations, the procedures needed by the study, and the possible benefits and risks of participating in the study. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You may also discuss it with your health care team. If you have any questions, you may ask your study doctor for more explanation. In this consent form, "you" refers to the patient.

A blood stem cell transplant is a standard treatment for blood cancers such as acute and chronic leukemias, lymphoma and myelodysplastic disorders. It replaces the abnormal (or diseased) blood cells with healthy cells from a donor. It requires a close tissue match between you and the donor. Your donor could be a family member, or it could be an unrelated person. The chemotherapy you get to destroy the abnormal cells and prepare your body for transplant is called the conditioning regimen. When lower doses of chemotherapy than usual are given, it's called a reduced-intensity conditioning regimen.

A common problem that may occur after a blood stem cell transplant is a condition known as Graft-Versus-Host Disease (GVHD). The "graft" is the donor blood cells that you will get during your transplant. The "host" is the person (in this case, you) receiving the cells. GVHD is when the donor graft attacks and damages some of your (the transplant recipient's) tissues.

- GVHD can cause skin rash, stomach (intestinal) problems such as nausea, vomiting, or diarrhea
- It may also damage your liver and cause hepatitis or jaundice (yellowing of the skin).
- GVHD may also increase your risk of infection.

2. How many people will take part in this study?

This study will include 22 participants.

3. What will happen if I take part in this study?

If you are eligible to take part in the study, agree to participate, and sign this Informed Consent Form, you will have the screening tests and procedures listed below. No study procedures will be done until after you sign this form.

We will check your health before you start treatment, while you receive treatment, and for 2 years after transplant.

Female subjects: We do not know if the study drugs will affect mother's milk or an unborn child. Therefore, breast-feeding and pregnant women are not allowed to take part in the study. Due to unknown risks and potential harm to the unborn child/ infant, you should not become pregnant or nurse a baby while on this study.

You must have a negative pregnancy test prior to enrolling in the study.

Unless you cannot have children because of surgery or other medical reasons (you had an effective tubal ligation: you had the ovaries or the uterus removed; or you are post-menopausal), you must use two effective methods of birth control or agree to practice true abstinence, from the time of signing the informed consent form, for the entire study drug treatment period (including interruptions in treatment), and for 90 days after completing study drug treatment. Periodic abstinence, meaning that you abstain from sex only on certain days of the months, and withdrawal are not acceptable methods of contraception. It is strongly recommended that at least one of these two methods be highly effective (see examples below).

Highly effective methods:
Intra-uterine devices (IUD)
Hormonal (birth control pills/oral contraceptives, injectable contraceptives, contraceptive patches

Other effective methods:
Barrier Latex or non-latex condom with or without a spermicidal agent
Diaphragm with spermicide; Cervical cap with a spermicide; Sponge with a spermicide.
If one of the highly effective methods cannot be used, using two effective methods at the same time are recommended.

Male subjects: We do not know if using the study drugs will affect sperm. Therefore, due to potential risk, you should not get your partner pregnant during the study drug treatment period (including interruptions in treatment). Even if you are surgically sterilized (i.e. have had a vasectomy) you must agree to use an appropriate method of barrier contraception (latex or non-latex condom with or without a spermicidal agent), or agree to practice true abstinence, during the entire study drug treatment period, and for 90 days after completing study drug treatment. Periodic abstinence, meaning that you abstain from sex only on certain days of the months, and withdrawal are not acceptable methods of contraception.

Highly effective methods:
Vasectomy

Other effective methods:
Barrier Latex or non-latex condom with or without a spermicidal agent Diaphragm with spermicide; Cervical cap

If one of the highly effective methods cannot be used, using two effective methods at the same.

Before You Begin the Study

Screening assessments performed within 4 weeks prior to start of transplantation

Before you begin the study, you will need to have medical examinations, tests, or procedures to find out if you can be in the study. Some of these examinations, tests, and procedures may be part of your regular medical care and may be done even if you do not take part in the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.
After you read this form, you will have a chance to discuss it with your family and friends. If you decide to participate in the study, you will be asked to sign this Informed Consent Form. No study testing or study evaluations will be done before you sign this consent form.
The following tests and assessments will be done at the first visit or within 30 days prior to the first visit:

- Medical history
- Physical examination, including blood pressure, pulse rate, respiratory rate and temperature, and weight
- Blood samples will be taken from a vein in your arm for laboratory blood tests. These tests will evaluate your blood counts, liver and kidney function, blood clotting ability, status of your myeloma, and any other safety evaluations.
- Blood samples will be taken to test for HIV, Hepatitis B and C, Epstein-Barr Virus (shingles) and Herpes Simplex Virus. State law requires positive test results for certain communicable diseases, including HIV, hepatitis, sexually transmitted infections, and tuberculosis, to be reported to a local health agency. Some of the tests for this study must be reported when positive. The study doctor can discuss this with you.
- Heart function tests, including EKG and ejection fraction.
- Lung (pulmonary) function tests.
- Tests to evaluate your cancer, including a bone marrow aspirate/biopsy. This is where samples of your bone marrow are taken from your hip bone with a needle.
- Imaging studies if needed depending on your disease
- A pregnancy test if you are a woman able to have children. If you are pregnant, you will not be able to take part in this study.

The initial screening visit may take approximately 3-4 hours, depending on clinic scheduling.

Other medications
If you require a vaccination, it is required that you receive it at least 4 weeks before receiving treatment. If you know that you will need a vaccination at any time during the study, please tell your study doctor. Please tell your doctor about all medication you are taking.

During the Study
If the examinations, tests, and procedures show that you can be in the study and you choose to take part, you will be enrolled into the study.

Before you begin the study:
If you agree to be in the study, you first sign this Informed Consent form, then you will be asked to participate in the assessments as listed below. Many of these tests and procedures are part of your regular medical care, but they may be done more often for this study.

Before the Transplant:
Before your transplant, your doctor will start the conditioning regimen. The conditioning regimen prepares your body for transplant. It uses chemotherapy to destroy the cancer cells and the cells that make up your immune system.

Details on the drugs we will give you prior to stem cell transplant are outlined below:

	Day -5	Day -4	Day -3	Day-2	Day-1	Day 0
Fludarabine 30 mg/m2 (in your vein)	X	X	X	X		
Melphalan 70 mg/m2 (in your vein)			X	X		
Stem Cell Transplant						X

Stem Cell Transplant
On your transplant day, the stem cells will be given to you through your central line, like a blood transfusion. The cells will travel through your bloodstream to your bone marrow where they will start to make healthy, new blood cells after several weeks.

After Your Transplant
The treatment that are used to prevent GVHD will start after you receive the donor stem cells. These treatments are a combination of drugs that hold back (suppress) your immune system and a standard component of the transplant.

You will start the maintenance treatment with Daratumumab between 90-150 days after stem cell transplant and it will continue for 1 year after the first dose as long as counts are acceptable (absolute neutrophil ≥1000/μL; Platelets ≥ 75,000/μL) and in the absence of

disease progression. You will receive daratumumab weekly at 16 mg/kg for 8 doses, followed by every 2 weeks for 8 doses, then monthly.

Health Evaluations after the Transplant (see Table 1)
We will test (evaluate) your health during the study. These tests and how often they are scheduled are standard care for patients receiving transplant. They would be done even if you were not part of this study. You will be watched closely for any signs and symptoms of GVHD.

Table 1: Schedule for Health Evaluations after Transplant

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 10	Month 3	Month 6	Year 1	Year 1.5	Year 2
Vital Signs	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Score of ability to carry out usual activities	x			x			x				x	x	x	x	x
Complete blood count	x	x	x	x					x		x	x	x	x	x
Blood test to check the function of your organs	x	x	x	x					x		x	x	x	x	x
Blood test to check your ability to fight infections											x	x	x	x	x
Blood test to check the recovery of your immune function & Other Related studies				x							x	x	x		
Blood test to monitor levels of your white blood cells	x	x	x	x	x	x	x	x	x	x	x	x	x		
Monitoring for side effects	x	x	x	x	x	x	x	x	x	x	x	x	x		
Acute Graft vs. Host Disease assessment	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Bone marrow biopsy & aspirate (response assessment)											x		x		x

This table outlines the different tests and procedures you will undergo while on this study. Each 'X' means that you will have that test or procedure on that particular time.

4. How long will I be in the study?

You will be in the study for 2 years after your transplant.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

You will have side effects while on the study. Side effects can range from mild to life-threatening. The risks and discomforts from this study are similar to what you would have even if you do not join this study. If you do, the effect on you might be better, worse or about the same. Your health care team may give you medicines to help lessen side effects such as feeling sick to your stomach (nausea). In some cases, side effects can be long lasting or may never go away.

Fludarabine

Likely (May happen in more than 20% of patients)	**Less Likely** (May happen in 20% or fewer patients, but more than 3%)	**Rare, but Serious** (May happen in 3% or fewer patients)
• Anemia (low red blood cells) which may require blood transfusions • Cough • Feeling tired or irritable • Infection, especially when white blood cell count is low • Low platelet counts, which may cause bruising or bleeding • Pain	• Chills • Confusion • Damage to brain, lungs, or other organs. This may cause tiredness, changes in thinking or shortness of breath • Feeling of "pins and needles" in arms and legs • Nausea, vomiting, loss of appetite • Sores in mouth which may cause difficulty swallowing	• Blood in urine • Changes in vision • Kidney damage which may require dialysis • Liver damage • Seizures

Melphalan

Likely (May happen in more than 20% of patients)	**Less Likely** (May happen in 20% or fewer patients, but more than 3%)	**Rare, but Serious** (May happen in 3% or fewer patients)
• Anemia (low red blood cells) which may require blood transfusions	• Inflammation of blood vessels • Kidney problems which may	• A new cancer • Allergic reaction which may cause rash, low

• Diarrhea • Feeling tired • Infection, especially when white blood cell count is low • Nausea, vomiting • Sores in mouth which may cause difficulty swallowing • Swelling of the body	require dialysis • Liver problems which may cause yellow eyes or skin • Low platelet counts, which may cause bruising or bleeding • Scarring of the lungs which may cause shortness of breath	blood pressure, wheezing, shortness of breath, swelling of the face or throat • Heart failure which may cause shortness of breath, swelling of ankles, and tiredness

Mycophenolate mofetil (MMF)

Likely (May happen in more than 20% of patients)	**Less Likely** (May happen in 20% or fewer patients, but more than 3%)	**Rare, but Serious** (May happen in 3% or fewer patients)
• Birth control may not work as well • Damage to unborn baby if you become pregnant while taking this medicine • Difficulty breathing, cough • Headache • High blood pressure • Low white blood cell count with increased risk of infection • Nausea, vomiting, diarrhea, stomach pain • Swelling of the hands, feet, ankles, or legs • Tremors	• Anemia (low red blood cell count) • Change in the levels of salts in the blood • Decreased platelet count, may cause blood loss into stool or vomit, increased bruising • Difficulty falling asleep or staying asleep • Dizziness • Low blood pressure • Pain in joints or muscles • Rash	• A new cancer • Change in vision • Encephalopathy or brain dysfunction that can lead to death • Excessive tiredness • Fast heart beat • Progressive Multifocal Leukoencephalopathy– This is caused by a virus that damages the protective covering in the brain. • Severe difficulty breathing • Weakness

Cyclophosphamide

Likely (May happen in more than 20% of patients)	**Less Likely** (May happen in 20% or fewer patients, but more than 3%)	**Rare, but Serious** (May happen in 3% or fewer patients)
• Absence of menstrual cycles which may decrease the ability to have children • Blood in urine • Feeling tired • Hair loss, skin changes, rash, change in nails • Infection, especially when	• Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Decrease in platelets which may cause bleeding • Decrease in red blood cells,	• A new cancer • Damage to the heart or heart failure which may cause shortness of breath, swelling, cough or tiredness • Scarring of the lungs which may cause

white blood cell count is low • Nausea, vomiting, diarrhea, loss of appetite, pain in belly • Sores in mouth	which may require blood transfusions • Loss or absence of sperm which may lead to an inability to father children	shortness of breath, fluid around the lungs • Swelling of the brain which may cause dizziness, confusion

Tacrolimus

Likely (May happen in more than 20% of patients)	**Less Likely** (May happen in 20% or fewer patients, but more than 3%)	**Rare, but Serious** (May happen in 3% or fewer patients)
• Abnormal body movement, including tremors • Abnormal levels of sugar, fat, or minerals (like sodium or potassium) in your blood • Constipation, diarrhea, nausea, vomiting, reflux, lack of desire to eat • Difficulty sleeping • Dizziness • Feeling of "pins and needles" in arms and legs • Headache • High blood pressure which may cause dizziness, chest pain • Itching, rash • Kidney damage which may cause swelling, may require dialysis • Low red blood cell counts, which may cause tiredness, or may require blood transfusions • Low platelet levels, which may cause bruising, bleeding • Low white blood cell counts, which may lead to infection • Liver damage • Swelling of the body	• A new cancer • A tear or a hole in your bowels which may cause belly pain and may require surgery • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Change in the heart rhythm, abnormal heartbeat, or heart stops beating • Damage to brain, which may cause headache, seizure, blindness • Damage to lungs, which may cause shortness of breath, fluid around lungs • Heart attack or heart failure which may cause chest pain, swelling of ankles, and tiredness	• Damage to small blood vessels with resulting small blood clots and possible organ damage

Daratumumab

Very Common (affects more than 1 in 10 patients)	Common (affects 1 to 10 in 100 patients)	Uncommon (affects 1 to 10 in 1,000 patients)
• Infusion related reaction (see separate section) • Infection of the upper respiratory tract infection such as nose, sinuses throat or airway • Infection of the lung • Low neutrophils (a type of white blood cell) • Low platelets • Low red blood cells • Low lymphocytes (a type of white blood cell) • Numbness/tingling of the hands, feet or limbs • Headache • Cough • Shortness of breath • Diarrhea • Nausea • Vomiting • Muscle spasms • Fatigue • Fever • Swelling of hands, feet or limbs	• Flu like symptoms • Sepsis (a life-threatening condition that arises when the body's response to an infection injures its own tissues and organs) • Irregular heartbeat	• Shingles (Herpes zoster) • High blood pressure • Low oxygen in the body • Swelling of the throat • Inflammation of lung tissue (pneumonitis) • Fluid in lungs (pulmonary edema) • Difficulty with blood testing prior to blood transfusion (Indirect Antiglobulin Testing positive)

Infusion-Related Reactions

Infusion–related reactions were reported in approximately half of all patients treated with daratumumab. It usually occurs with the first infusion and during or within the first few hours of the start of the infusion.

Signs and symptoms of infusion-related reactions may include respiratory symptoms, such as stuffy nose, cough, throat irritation, as well as chills, vomiting and nausea. Less common symptoms are having trouble breathing (wheezing), runny nose, fever, chest discomfort, itching of the skin, and low blood pressure or high blood pressure. Most of the observed infusion-related reactions so far were mild or moderate, and ended by temporarily stopping the infusion and giving medicines to treat the side effect.

Severe reactions include narrowing and obstruction of the respiratory airway (bronchospasm), low oxygen, shortness of breath, high blood pressure, swelling in the throat and fluid accumulation in the lungs (pulmonary edema).

7. What benefits can I expect from being in the study?

Taking part in this study may or may not benefit you. The results of this study may help researchers learn things to better treat future Multiple Myeloma patients.

8. What other choices do I have if I do not take part in the study?

Taking part in this research study is voluntary. Instead of being in this research study, you have other options which may include the following:

- Taking part in another research study, if one is available
- Receiving standard of care treatment
- Receiving comfort care, also called palliative care. This type of care may help to reduce the symptoms caused by cancer, but does not treat the cancer directly
- Receiving no treatment

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

You and/or your insurance company will be financially responsible for any hospital inpatient, outpatient, and follow-up visits that would normally or routinely as part of your standard of care treatment. This could include charges for treatments, medications, physician visits, laboratory tests, and procedures. You and/or your insurance company will be responsible for these routine charges. You will be responsible for any costs not covered by your insurance company, including deductibles, co-payments, and all out of pocket expenses. Before you agree to be in this study, you should contact your health insurer to see if your plan will cover the costs required as part of your participation.
There may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the study visits.

Participation in this study is not a substitute for health insurance.

10. Will I be paid for taking part in this study?

You will not be paid to take part in this study.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information be used or shared for future research?

No

14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- Your insurance company (if charges are billed to insurance).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time by entering the NCT number NCT04205240.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  HIV / AIDS
  Hepatitis infection
  Sexually transmitted diseases
  Other reportable infectious diseases
  Physical exams
  Laboratory, x-ray, and other test results
  Diaries and questionnaires
  The diagnosis and treatment of a mental health condition
- Records about any study drug you received;

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record.

IV. Your information may be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact **Dr. Srinivas Devarakonda, MD at (614) 366-5539or (614) 293-3196or (614) 293-8000 (24 hours).**

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact ***HIPAA Privacy Manager, The Ohio State University Medical Center, Suite E2140, 600 Ackerman Road, Columbus, OH 43202 or at 614-293-4477***.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **Dr. Srinivas Devarakonda, MD, at (614) 366-5539or (614) 293-8000 (24 hours).**

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of participant	**Signature of participant**
	AM/PM
	Date and time
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)**
	AM/PM
Relationship to the participant	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	Signature of witness _____ AM/PM Date and time
Printed name of witness	Signature of witness _____ AM/PM Date and time