Are you participating in any other research studies? _____ Yes _____No

Concise Summary: This research study tests a new medicine for mobilizing stem cells (helping push stem cells out of the the bone marrow into the blood) so they can be collected and used for autologous stem cell transplant for treatment of your multiple myeloma. This investigational medicine (MGTA-145) will be given with plerixafor. Plerixafor is approved by the United States Food and Drug Administration (FDA) for mobilizing stem cells and is currently given with another medicine called G-CSF (granulocye colonly stimulating factor). The combination of MGTA-145 and plerixafor in this study is investigational. We think giving you the MGTA-145 with plerixafor will allow us to collect the necessary number of stem cells for your future transplant in less time and with less side effects than the standard mobilization procedure of plerixafor and G-CSF. Usually the plerixafor and G-CSF must be given over 4 or 5 days before the stem cell collection (called 'apheresis'). Chemotherapy may also be given to help 'mobilize' stem cells and it also requires several days to mobilize the stem cells. Both of these standard methods can require several days of blood collection (apheresis).

In this study plerixafor and MGTA-145 will be followed by the stem cell collection on the same day, and both may be repeated the next day, for a maximum of two days. If successful, the benefit of this approach is it will also allow us to shorten the number of apheresis collections to only two days. This approach could limit side effects that may occur with medicines like G-CSF.

This approach is experimental as MGTA-145 is not approved by the FDA. MGTA-145 has been studied in healthy volunteers, when given alone and when given with with plerixafor. It has shown promising results for stem cell mobilization. Overall, it was found to be safe. In the group of healthy volunteers who were given MGTA-145 alone, 80% reported back pain, which was short lived and went away within 20 minutes in the majority of people. Amongst healthy volunteers who received MGTA-145 and plerixafor, people also reported brief periods of back pain. Another side effect reported with this combination was diarrhea, which is commonly observed with plerixafor. Side effects of MGTA-145 and plerixafor are listed in detail later in this document. No new or unexpected side effects were seen with the combination of plerixafor and MGTA-15 in the study of healthy volunteers.

If the number of stem cells needed for your transplant cannot be collected with this investigational combination of medicines, your doctor may ask you to have another approach for collecting stem cells, which may require that you take a break

to let your bone marrow recover before having another stem cell mobilization and apheresis procedure.

After stem cell collection, we will ask you to come back for a clinic visit within one week. If you are not planning a stem cell transplant within two months after the cell collection, we will call you one month after collection. If you don't have any side effects from the collection at that time, no further follow-up is needed on this study.

If you and your doctors are planning a stem cell transplant within two months of stem cell collection, we will follow you in clinic and with phone calls for up to four months after the transplant, as described below.

Participation in this study is voluntary. If you chose not to participate, your doctor will consider alternative approaches for mobilizing your stem cells before apheresis including G-CSF and plerixafor or chemotherapy and G-CSF, with plerixafor if needed. These are described in detail in this consent.

PURPOSE OF RESEARCH

You were selected as a possible participant in this study because you have multiple myeloma and are being considered for an autologous stem cell transplant, either in the immediate future or later in your disease course. To prepare for the transplant we need to collect special cells called 'hematopoetic stem cells'.

All of the cells of the immune system including red cells, white cells and platelets are made in the bone marrow. All of these cells develop from a type of cell found in the bone marrow called a "hematopoietic stem cell." This is the type of cell collected for blood and marrow transplantation. In order to collect enough hematopoietic stem cells from the bone marrow to make a successful transplant, we have to move the cells from the bone marrow to the blood. Once they are in the blood, they can be collected during a procedure called 'apheresis'. Currently this requires several days of different medicines (4-5 days) and several days of apheresis. In this study you will be given an investigational medicine (MGTA-145) in combination with an FDA approved medicine called plerixafor. Currently plerixafor given with granulocyte colony stimulating factor or G-CSF is the procedure approved by the FDA for stem cell collection. In this study you will not receive G-CSF.

The MGTA-145 is being provided by Magenta Therapeutics, the study medicine's manufacturing company and will be provided to you at no charge.

We hope to learn whether the combination of MGTA-145 and plerixafor, given on the same morning as stem cell collection for up to two days, allows us to collect enough stem cells to do an autologous stem cell transplant. We will also evaluate the side effects of this new medicine combination and whether there is any effect on the transplant, including engraftment (the repopulation of normal blood cells with the infused stem cells) and myeloma response, for up to three months after your transplant. We will also ask you questions about your pain and how you are feeling after receiving the MGTA-145 and plerixafor.

If you consent to participate in this study, the study team will review your treatment history and results of laboratoty tests and other tests ordered by your transplant doctor as part of your transplant evaluation. This is to determine whether you meet the criteria to receive MGTA-145.

If you meet the criteria, you will first be given plerixafor as a shot or injection under the skin, followed 2 hours later by the investigational study drug (MGTA-145), which is given as an intravenous (IV) infusion (into a vein in your arm). This infusion will take up to ten minutes. Following MGTA-145, you will start the stem cell collection procedure (apheresis). This procedure will last at least 4.5 hours and up to 6 to 7 hours, depending on your height and weight. Your blood will be drawn through a needle in your arm or through a central venous catheter (CVC) and will then pass through an apheresis machine, which identifies stem cells by targeting a marker on them called CD34. The medicines and apheresis may be repeated the next day depending on the number of stem cells collected. The goal is to collect at least 2 million CD34+ stem cells/kg of your body weight in two days.

If enough cells are not collected on these two days, your physician may ask you to use another method for mobilizing stem cells after after you have a rest.

You can decide to stop participation at any time during this study. If you decide to stop participating in this study, you should notify

Surbhi Sidana, MD
300 Pastuer Drive H0101c
Stanford, CA 94305
Phone Number: 650-723-0822
Email: surbhi.sidana@stanford.edu

This research study is looking for 25 people with multiple myeloma who need stem cells collected for autologous stem cell transplantation. At this time, this study is only open at Stanford University.

After one to two days of MGTA and plerixafor followed by stem cell collection, you will not receive any further investigational agent. The remainder of the procedures, including transplant will be done according to Stanford University Blood and Marrow Transplantation (BMT) Division's standard institutional practice.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 24 months to recruit all participants and report results.

Your active participation in the study including the medicines for cell mobilization, apheresis, clinic visits or phone calls is for a duration of two to six months.

If you are scheduled for transplant within two months of stem cell collection, we will see you in clinic and call you on the phone for up to four months after your transplant. If you are NOT planning a transplant within two months of collecting your stem cells, we will follow you for up to one month after stem cell collection, including clinic visits/phone calls.

After the active follow-up period, which includes clinic visits/phone calls, we may continue to collect information on your health status, myeloma treatment and transplant history from your electronic medical record periodically, whichever is later. If these stored stem cells are shipped to another medical center for a stem cell transplant, we will request that center send us medical records about your stem cell transplant after getting your authorization to do so.

PROCEDURES

If you choose to participate, Surbhi Sidana, MD, the Protocol Director and her research study staff will consent you to the study.

The study is divided into three phases:

1. Pre-mobilization phase:

After you sign informed consent, you will have a physical examination, blood tests and other tests that are routinely done before stem cell collection and transplant per Stanford University BMT Division's guidelines and standard practices. The study team will review the results of these tests, as well as review your medical history and myeloma treatment history to determine whether you are eligibile to participate in the study and proceed with stem cell mobilization.

2. **Mobilzation phase:** This phase of the study is the only phase which involves the investigational/experimental medicine. A summary is provided in **Table 1.**

On your scheduled day of stem cell mobilization, you will receive plerixafor injection under the skin (subcutaneously), followed two hours later by MGTA-145, which is given by vein (IV - intravenously) over 3 to 10 minutes. A few minutes after that you will start the stem cell collection procedure/ apheresis, which will last at least 4.5 hours and may last up to 6-7 hours depending on your height and weight. Our goal is for the machine to circulate and process your entire blood volume at least three times to collect enough stem cells.

Apheresis or stem cell collection is done through a peripheral intravenous catheter (small plastic tube in your arm) or a central line, which is a intravenous line placed in your neck. The decision regarding the type of approach used for stem cell collection is made by your treating physician and the apheresis team. Participation in this study will not impact the choice of catheter used for apheresis.

You will have at least three blood samples drawn on each day of mobilization/stem cell collection. The first sample will be collected in the

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Approval Date: August 17, 2021
Expiration Date: August 17, 2022

morning, the second one will be collected approximately 15-30 minutes after MGTA-145 infusion and the third at the end of apheresis. Additional samples may be collected if anything is not normal. This is according to Stanford BMT standard guidelines and is not specific to this research.

We will also ask you questions about side effects you have and ask you to fill out questionnaires on each day of stem cell collection and in the follow-up clinic visit after stem cell collection. These questionnaires pertain to side effects, pain and quality of life during collection.

The stem cells collected will be processed per Stanford BMT/Cell Therapy Facilty standard procedures for evaluating the stem cell count and for cryopreservation i.e storage under very cold temperatures. This is done for all stem cell collections in patients with myeloma.

A part of the collected stem cell product, about 15 mL will be stored for research purposes. The goal of these research tests is to understand the nature and effectiveness of the stem cells collected with this new technique and other cells or components that are present in the collected stem cell product.

Table 1: Study Medicines and Stem Cell Collection Procedures

Medication/Procedure	**Day 1**	**Day 2 (If needed)**
Plerixafor	One dose given subcutaneously	Same as day 1
MGTA-145 **(Investigational medicine)**	One dose given as an intravenous infusion over 3 to 10 minutes. This will be given 2 hours after plerixafor.	Same as day 1
Apheresis procedure to collect stem cells	At least 4.5 hours and can last upto 6-7 hours depending on your height and weight. Remaining details of this procedure will be per Stanford University BMT division's standard practices.	Same as day 1
Questionnaire asking about symptoms	After receiving MGTA-145	Same as day 1

Participant ID:

STUDY

Blood Samples	At least three blood samples: Before receiving plerixafor for routine blood work (standard practice) After receiving MGTA-145 to check CD34 count (research) After stem cell collection to check CD34 count (research) Additional samples as clinically needed for your care	Same as day 1

3. Follow-up phase

The follow up procedures will be slightly different depending upon when you and your transplant doctor plan for you to receive the stem cell transplant:

Patients not planning a stem cell transplant within two months of stem cell collection: You will be asked to follow-up in clinic within one week after stem cell collection. This is routinely done as part of follow-up after collection. You will receive a follow-up phone call one month after stem cell collection. Additional follow-up may be needed if you experience any side effects related to collection that are still present at that time. Beyond this point, we may periodically review your medical records to get information about your myeloma treatment and overall health or when you come back for a transplant using the stored stem cells.

Patients planning to proceed with stem cell transplantation within two months of stem cell collection: All procedures, treatment and follow-up related to stem cell transplant will be done per standard practices of the Stanford BMT Division.

In addition we will look at the following data to see if the investigational medicine for mobilizing stem cells affects your transplant course:

We will check your blood counts to see how long it takes them to recover after transplant. We will also collect other details pertaining to transplant and myeloma response.

You will be asked to come to clinic around one month and three months after transplant as part of study follow-up. This is routinely done as part of follow-up for transplant patients. A research blood sample will be taken along with your usual tests. This research sample involves collection of 15 mL of blood, which is approximately one tablespoon.

A bone marrow biopsy is typically done as part of routine care two to three months after stem cell transplant. If you are undergoing a bone marrow aspirtate and biopsy after transplant at Stanford University, we will also collect an extra research sample from the bone marrow aspirate. This sample will be 5 mL or one teaspoon.

Additional follow-up may be needed if you are still experiencing side effects that are thought to be related to the investigational drug. Beyond this point, we may periodically evaluate your medical records to monitor your myeloma treatment and general health.

This research will not include whole genome sequencing. Any of your specimens which are used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, Stanford University and/or others. However, donors of specimens do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries.

Future Use of Private Information and/or Specimens

Research using private information and/or specimens is an important way to try to understand human disease. You are being given this information because the investigators want to save private information and/or specimens for future research. Magnenta Pharmaceuticals, the company manufacturing the MGTA-145 may receive your study information and some of your study samples as part of this research.

A part of your specimens will be stored under very cold temperatures in the labs at Stanford BMT Division and Cell Therapy Facility. Your specimens will be stored frozen with your study identification number, not your name or other information that can identify you personally. Only the investigator and study team have access to the information linking you to your study identification number, which is kept secure in a locked file or password protected secure server.

Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or gotten your partner pregnant.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Surbhi Sidana, MD at 650-723-0822 with a verbal request to withdraw from the study or submit a verbal or written request to the study team or your Stanford BMT doctor.

If you withdraw from the study before stem cell collection, no treatment with MGTA-145 will be given. Your team will continue your routine clinical care

IRB Use Only
Approval Date: August 17, 2021
Expiration Date: August 17, 2022

The Protocol Director may also withdraw you from the study and the study medication may be stopped, without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- You need treatment not allowed in the study, include need for stem cell mobilization with other treatments.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

MGTA-145:

In healthy volunteers receving MGTA-145, the most common side effect with MGTA-145 was lower back/muscle pain seen in the majority of (60-80%) of volunteers. Back pain was usually short lived and improved without any medication within 20 minutes in the majority of patients. When MGTA-145 was used in combination with plerixafor in healthy volunteers, other side effects were reported as listed below. Overall the drug combination was considered safe, with mild side effects.

Frequent/most common side effects (seen in more than 10% of volunteers) after treatment with MGTA-145 and plerixafor

- Back pain/musculoskeletal pain
- Diarrhea
- Nausea
- Dizziness
- Abdominal pain
- Headache

Less common side effects (seen in less than 10% of volunteers)

IRB Use Only
Approval Date: August 17, 2021
Expiration Date: August 17, 2022

- Vomiting
- Abnormal tingling sensation
- Fatigue
- Abdominal discomfort
- Chest pain
- Muscle/bone pain

Allergic and infusion related reaction to MGTA-145 are also possible, though not observed in humans yet. It is also possible that you develop an antibody to MGTA-145, though it has also not been observed in humans yet.

As we are testing a new drug, it may involve risks which are currently unforeseeable.

Plerixafor:

The most common side effects (≥10%) in patients who received plerixafor with G-CSF in clinical studies were:

- Diarrhea
- Nausea
- Fatigue
- Injection site reactions
- Headache
- Joint Pain
- Dizziness
- Vomiting

Less common (<10%)

- High white cell count
- Difficulty sleeping
- Flatulence

Rare:

- Spleen enlargement/ spleen rupture
- Passing out/nearly passing out
- Allergic reactions with plerixafor are seen in less than 1% of patients.

Women of Childbearing Potential

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk.

To confirm to the extent medically possible that you are not pregnant, you agree to have a pregnancy test done before beginning this research study.

You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

If you are a man participating in this study and your partner is able to become pregnant, you and your partner must use adequate (at least two methods of highly effective) contraception while you are participating in the study and for at least 90 days after administration of study medication.

You should also agree to not donate sperm for at least 90 days after administration of study medication. Your doctor will discuss with you what methods of birth control are considered adequate. You should inform your study doctor if your partner becomes pregnant.

POTENTIAL BENEFITS

A potential benefit of this study is that stem cell mobilization and collection will be completed in two days without any significant additional side effects. Tranditional methods can take several additional days to mobilize and collect stem cells.

However, we cannot and do not guarantee or promise that you will receive any benefits from this study.

ALTERNATIVES

You may chose to undergo stem cell mobilization and collection with alternative strategies that are available. Two common strategies include:

1) **Chemotherapy and GCSF (granulocyte colony simulating factor) based mobilization with as needed use of plerixafor:** In this method, you are given intravenous chemotherapy, typically cyclophosphamide over one day. You have to come to the treatment center for tests and IV fluids one day before and one day after the chemotherapy. After chemotherapy is given, you are given daily G-CSF and asked to do daily blood count checks. Your blood counts drop over the first few days and then gradually start coming up. Once your blood counts come up beyond a certain number (typically two weeks after chemotherapy), we ask you to come in to get a CD34 count (stem cell count) checked. If CD34 count is adequate per institutional requirements, you may start stem cell collection the next day. If it is not adequate, your doctor may decide to treat you with plerixafor before stem cell collection. You will continue GCSF and plerixafor (if it has been added) on each day of stem cell collection. If CD34 counts are not high enough either before colletion starts or with collection, your doctor may make a decision to abandon the proedure and proceed with alternative methods.

   The benefit of stem cell collection with this procedure is that it has been used for a long time for stem cell collection before transplant in myeloma and is a well established method.

   Risks with this method include the risks that come with chemotherapy, including risk for fever and infectious complications when your blood counts are low, potential need of blood product transfusion, as well small risks for kidney and other organ damage. Other side effects include bone pain and night sweats from G-CSF. If plerixafor is used, additional side effects related to plerixafor may occur as described above, including diarrhea.

2. GCSF with on demand plerixafor: In this method you are given four days of injections with G-CSF, which is given subcutaneously i.e under the skin. On the fourth day, we check stem cell CD34 counts. If they are below the a certain number, you are given plerixafor subcutaneously and start stem cell collection procedure the next day. You continue both G-CSF and plerixafor on each day of collection. About half the patients will receive plerixafor based on our experience and published literature.

Side effects with GCSF include bone pain, low grade fever and night sweats and the rare chance of serious organ damage like spleen rupture. Side effects with plerixafor are described above including diarrhea, which is the most common side effect. These side effects typically resolve within a few days of stopping these medications.

The benefit of stem cell collection with this procedure is that it has been used for a long time for stem cell collection before transplant in myeloma and is a well established method. The disadvantage is that you need four days of GCSF injections before collection. After four days of injection, the collection period can vary from one day to up to four or five days of collection.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

ClinicalTrials.gov

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

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain information on the safety and effectiveness of MGTA-145. The data and information regarding your participation in this study will be provided to Magenta Therapeutics, the company who is providing the drug. In addition information may be provided to the Food and Drug Administration and other federal and regulatory agencies as required.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Center for Advancing Translational Sciences which is funding this project 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 from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of such as child abuse and neglect, or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document. Please refer to the section entitled "**What Personal Information Will Be Obtained, Used or Disclosed?**".

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

This is a clinical trial studying a new drug called MGTA-145 in combination with plerixafor to collect stem cells in prepeparation for autologous stem cell transplant in multiple myeloma. Results of this study, which includes de-identified patient information about how well this combination worked, side effects, treatment history and outcomes with transplant will be reported in scientific presentations and publications. The information will also be submitted to Magenta Therapeutics, which is providing the drug, and the FDA.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study)

at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to:

Surbhi Sidana, MD
300 Pastuer Drive H0101c
Stanford, CA 94305
Phone Number: 650-723-0822

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to demographics, medical history, physical examination findings, myeloma diagnosis, treatment and response, laboratory reports include blood/urine tests and pathology reports, imaging reports, reports of procedures including echocardiogram and lung function tests and medical history.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director (Surbhi Sidana, MD)
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

IRB Use Only
Approval Date: August 17, 2021
Expiration Date: August 17, 2022

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- Magenta Therapeutics
- The United States Food and Drug Administration
- National Institutes of Health

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on December 31, 2045 or when the research project ends, whichever is earlier.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____
Print Name of LAR

_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

IRB Use Only
Approval Date: August 17, 2021
Expiration Date: August 17, 2022

FINANCIAL CONSIDERATIONS

Payment/Reimbursement
You will not be paid to participate in this research study.

Costs
If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the study that are not a part of your routine medical care. However, 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. You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. You will not be charged for the MGTA-145. **You will also be responsible for any co-payments and/or deductibles as required by your insurance.** Participation in this study is not a substitute for health insurance.

Magenta Therapeutics is providing financial support and/or material for this study.

Consultative or Financial Relationships

Dr. Surbhi Sidana is a paid advisor to Magenta Therapeutics, Inc. the company sponsoring this research study.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, care will be provided to you. You will not be responsible for any of these costs.

If you receive Medicare benefits, and if the sponsor of this study pays for any study-related treatment, complications or injuries, personal information about you, your treatment, and your participation in this study will be provided to the sponsor, who is required by law to provide it to Medicare.

You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Surbhi Sidana, MD at 650-723-0822. You should also contact him/her at any time if you feel you have been hurt by being a part of this study.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____
Print Name of LAR

_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

_____ _____

Signature of Witness Date

_____

Print Name of Witness

(e.g., staff, translator/interpreter, family member)

- *Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.*
- *The English consent form (referred to as the "Summary Form" in the regulations):*
  - *Must be signed by the witness AND the Person Obtaining Consent (POC).*
  - *The non-English speaking participant/LAR does not sign the English consent.*
  - *The non-English speaking participant/LAR should not sign the HIPAA participant line*
  - *If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.*