



Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Administration of Expanded, Most Closely HLA Matched SARS-CoV-2-
Specific T Cells for the Treatment of COVID-19 Patients with Cancer
2020-0759

Study Chair: David Marin

Participant's Name

Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by the MD Anderson Institutional Review Board (IRB - a committee that reviews research studies). You may talk to them at (713) 792-6477 or IRB_Help@mdanderson.org if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

STUDY SUMMARY

If you are reading and signing this form on behalf of a potential participant, please note: Any time the words "you", "your", "I", or "me" appear, it is meant to apply to the potential participant.

The goal of this clinical research study is to learn if giving cytotoxic T lymphocytes (CTLs) can help to control the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus that causes corona disease (COVID-19). Researchers also want to learn about the safety of giving CTLs to patients with COVID-19.

CTLs are made from donated blood cells grown in the laboratory and are designed to kill viruses that can cause infections.

This is an investigational study. The use of CTLs to treat COVID-19 is not FDA approved. At this time, CTLs are only being used to treat infections in research studies. The study doctor can explain how CTLs are designed to work in more detail.

The CTLs may help to control COVID-19. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. If you take part in this study, you may experience side effects, some of which may be severe or fatal. You may choose not to take part in this study because it is a first in human study.

You can read a list of potential side effects below in the Possible Risks section of this consent.

You may receive 1 infusion of CTLs. Your participation in this study will be over about 3 months after the CTL infusion.

The collection and making of the CTLs, as well as the blood tests for genetic testing, will be performed at no cost to you. You and/or your insurance provider will be responsible for the cost of infusing the cells and all other tests and procedures in this study.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive the standard of care for the infection. You may choose to receive other investigational therapy, if available. The study doctor will discuss the possible risks and benefits of these treatments. You may choose not to have treatment at all. In all cases, you will receive appropriate medical care.

1. STUDY DETAILS

Screening Tests

Signing this consent form does not mean that you will be able to take part in this study. The following tests and procedures will be performed to help the doctor decide if you are eligible:

- Your study doctor will ask about your medical history to see if you have risk factors that may increase the risk of complications caused by COVID-19 infection.
- Blood (about 4 tablespoons) will be drawn for routine tests and to confirm that you have COVID-19. If you have COVID-19, this sample will also be used to check for inflammation. If you can become pregnant, part of this sample will be used for a pregnancy test. To take part in this study, you must not be pregnant.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other options will be discussed with you.

Up to 52 participants will be enrolled in this study. All will take part at MD Anderson.

CTL Administration

If you are found to be eligible to take part in this study, you will receive CTLs by vein over about 2-10 minutes. If you are receiving the CTLs as an outpatient, you will stay in the clinic for about 1 hour after the CTL infusion so that you can be checked for any side effects you may have. If you are admitted in the hospital, you will receive the CTLs in your room.

You will be given standard drugs to help decrease the risk of side effects. You may ask the study staff for information about how the drugs are given and their risks.

You will no longer be able to receive the CTL infusion if the infection gets worse before the infusion, if you need medical treatment not allowed in this study, or if you are unable to follow study directions.

Study Visits

The study visit time points are based on the time of your CTL infusion.

Within 72 hours before the CTL infusion:

- You will have a physical exam and will be asked about COVID-19 infection symptoms. If you are not admitted to the hospital, you may have a remote visit over a video call. A member of the study team will discuss this with you.
- Blood (about 7 tablespoons) will be drawn for routine testing, to test for the virus, to check for inflammation, and for genetic testing. The genetic testing in this study is done to learn more about the infection and your response to the CTL infusions.
- If you are in the hospital, the level of oxygen in your blood will be measured. This will be done either with a painless clip that is attached to your finger or with a blood draw (about 1 teaspoon). You will have a chest x-ray or CT scan of your chest.

If you are admitted to the hospital for the CTL infusion, you will have a physical exam and blood (about 5 tablespoons) will be drawn for routine tests every day until you are discharged from the hospital.

On Days 7 and 21 after the CTL infusion:

- You will be asked about COVID-19 infection symptoms and oxygen requirements. If you are not admitted to the hospital, you may have a remote visit over a video call.
- If you are in the hospital, the level of oxygen in your blood will be measured. This will be done either with a painless clip that is attached to your finger or with a blood draw (about 1 teaspoon).
- You will have standard of care tests to check the status of graft versus host disease (GVHD - a condition in which transplanted tissue attacks the body into which it is transplanted). This will be explained to you as part of your standard care.

- Blood (about 8 tablespoons) will be drawn for routine testing, to check for virus, to test the effect of the CTLs on the virus and your immune system, and for genetic testing. If you have COVID-19, this sample will also be used to check for inflammation.

On Days 14 and 28:

- You will have a physical exam. If this exam is not performed, you may have a remote visit over a video call to check on you. A member of the study team will discuss this with you.
- If you are in the hospital, the level of oxygen in your blood will be measured. This will be done either with a painless clip that is attached to your finger or with a blood draw (about 1 teaspoon).
- Blood (about 2 teaspoons) will be drawn for routine tests.
- You will have a chest x-ray or CT scan of your chest.

About 3 months after the infusion:

- A research nurse will call to ask you about COVID-19 symptoms and if the infection has come back, your oxygen needs, and symptoms you may have experienced after the infusion. The call should take about 5-10 minutes.
- Blood (about 8 tablespoons) will be drawn for routine testing, to check for virus, to test the effect of the CTLs on the virus and your immune system, and for genetic testing. If you have COVID-19, this sample will also be used to check for inflammation.

Other Information

While on study, you should avoid taking any steroids because they may affect how the CTLs work. You should tell your study doctor right away if you take any steroids.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. These side effects will vary from person to person. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You should discuss these with the study doctor. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after treatment is stopped, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Tell the study staff about any side effects you may have, even if you do not think they are related to the CTLs/ study procedures.

CTLs may cause inflammation, which may result in fever, flu-like symptoms, swelling, liver damage, and/or kidney damage. CTLs may cause GVHD.

The processing procedures may accidentally introduce tiny organisms (such as bacteria) into the blood that could cause infection after the CTLs are infused. Every effort will be made to try to check for infection and prevent against it.

The CTL infusion may cause cytokine release syndrome (CRS). This involves a release of a large amount of proteins into the blood stream. This may cause changes in blood pressure and heartbeat, flu-like symptoms (nausea, fever, and chills) and/or affect your lung/liver/kidney function. It may also cause certain brain-related symptoms, such as dizziness, weakness, confusion, difficulty speaking, and/or decreased brain function (possible paralysis and/or coma).

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

CT scans send x-rays through the body at many different angles. You will be exposed to a small dose of radiation. All radiation adds up over a lifetime and may increase the risk of new cancer forming. Some people may feel "closed in" while lying in the scanner. However, the scanner is open at both ends, and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or radiology technicians will give comfort, or the scanning will be stopped. When a CT scan of the abdominal area is taken, material may be inserted into the rectum to better define the bowel. You will usually drink liquid to help define various abdominal organs. This may cause nausea and/or vomiting. Solution may also be given by vein to make the x-ray pictures more accurate. This may cause an uncomfortable feeling of warmth, nausea, and/or severe allergic reactions. The solution injection may also cause pain, bleeding, bruising, hives, and/or itching.

During the **MRI**, you may feel mild vibrations throughout your body. The machine will produce a loud knocking noise. This is normal. You will be given earplugs to protect your ears. Some people, especially those who tend to feel uncomfortable in small or closed spaces, may feel "closed in" and become anxious while in the scanner. The scanner has an intercom, which will allow you to speak to the staff during the procedure. If you feel ill or anxious during scanning, tell the MRI staff and the scanning will be stopped if you wish. The MRI will require a catheter to be inserted into one of your veins in order to inject the MRI contrast agent. This may cause skin irritation, bleeding, and/or infection. You may have an allergic reaction to the contrast agent.

The magnetic field used in MRI scanning may harm you if you have certain types of metal in your body (as might be found in pacemakers, neurostimulators, or certain clips). It may cause problems with devices, such as pacemakers. If you have metal in your body or devices such as a pacemaker, you should discuss this with the study doctor.

You may feel a coolness on your skin from the gel on the wand and a slight pressure of the wand on your chest during an **ECHO**.

Genetic research may result in the development of beneficial treatments, devices, new drugs, or patentable procedures. There are no plans to provide you compensation from such developments. The results of any genetic tests may be put in your health records. If this information were released, it could be misused. Such misuse could be

distressing, and it could cause you or your family members to have difficulty obtaining insurance coverage and/or a job.

A federal law called the Genetic Information Nondiscrimination Act (GINA) makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Nor does this federal law prohibit discrimination based on an already known genetic disease or disorder.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks

Taking part in this study can result in risks to an unborn or breastfeeding baby, so you should not become pregnant, breastfeed a baby, or father a child while on this study. You must use birth control during the study if you are sexually active.

Birth Control Specifications: Talk to the study doctor about acceptable methods of birth control to use and how long to use them.

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy.

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away.

Getting pregnant will result in your removal from this study.

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr. David Marin, at 713-792-8750) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.
5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.
6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.
7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.
8. MD Anderson may benefit from your participation and/or what is learned in this study.

Future Research

Data

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and/or shared with other researchers and/or institutions for use in future research.

Samples

Samples (such as blood and/or tissue) are being collected from you as part of this study. Researchers at MD Anderson may use any leftover material that is stored at MD Anderson in future research.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

Genetic Research

Research samples collected from you as part of this study may be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment. If genetic research is done with your samples, those who have access to those samples may be able to identify you. The results of this research may also be able to be linked to you. The same level of data protection that covers your individual data does not apply to summary results (when data from the whole study is combined).

Authorization for Use and Disclosure of Protected Health Information (PHI):

- A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
- Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
 - The IRB and officials of MD Anderson

- future sponsors and/or licensees of the study technology
- Center for International Blood and Marrow Transplantation Research (CIBMTR) and National Marrow Donor Program (NMDP)
- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

- B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.
- C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

- D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.
- E. 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.

CONSENT/AUTHORIZATION
(Adult Participants Only)

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

SIGNATURE OF PARTICIPANT

DATE

PRINTED NAME OF PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol .

SIGNATURE OF WITNESS TO THE VERBAL CONSENT
PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR)

DATE

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

PERSON OBTAINING CONSENT

DATE

PRINTED NAME OF PERSON OBTAINING CONSENT

PARENT/GUARDIAN PERMISSION

I have read and understand the description of this research. I have had a chance to discuss the study and ask questions. My questions have been answered. I give permission for my child or ward to take part in this study.

SIGNATURE OF PARENT/GUARDIAN

DATE

PRINTED NAME OF PARENT/GUARDIAN

SIGNATURE OF PARENT/GUARDIAN

DATE

Signature of Other Parent (Optional, unless required by the IRB.)

PRINTED NAME OF PARENT/GUARDIAN

____ The IRB has determined that the signature of both parents is required.

If not obtaining both parental signatures, please indicate reason below:

____ Other parent is deceased, unknown, incompetent, or not reasonably available.

____ Parent/Guardian signing above has sole legal responsibility for the care and custody of the child.

____ **X** The IRB has determined that the signature of both parents is NOT required.

ASSENT OF MINOR

(Entire section must be completed if the participant's intellectual age is at least 7 and less than 18 years. Participants with an intellectual age of 7 - 12 are not required to sign.)

If written assent is not obtained on an age-appropriate participant, check reason why not:

____ 1.) The participant's intellectual age is less than seven.

____ 2.) The participant dissented, but the participant's parent(s)/guardian felt that the intervention(s) or procedure(s) involved in the research hold out the possibility of a direct benefit that is important to the health and/or well being of the participant and is available only in the context of this research study.

____ 3.) Other: _____

I have been told what I will be asked to do in this study.

I have been told that I do not have to be in this study. If I decide not to be in this study, no one will be mad at me. I may quit at any time, but if I do, I may need to take a different treatment.

I have had a chance to talk about the study and ask the study doctor questions. All of my questions have been answered. I agree to be in this study and do what I am asked to do so long as I want to stay in this study. I agree that the study doctor can put me on this study. By signing this paper, I am not giving up any of my legal rights. I have been given a copy of this document.

SIGNATURE OF MINOR (Age 13-17)

DATE

PRINTED NAME OF MINOR

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into _____ and assisted the people
(Name of Language)

obtaining and providing consent by translating all questions and responses during the consent process for this participant.

NAME OF TRANSLATOR

SIGNATURE OF TRANSLATOR

DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line.)