INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Veronika Bachanova, MD – University of Minnesota / MT2019-46: FATE FT596 with Rituximab as Relapse Prevention in High Risk Patients after Autologous Hematopoietic Stem Cell Transplantation for Non-Hodgkin Lymphoma**
Protocol Number:	**2019LS230 (MT2019-46)**
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Financial Interest Disclosure: This research is supported in part by Fate Therapeutics. The University of Minnesota has licensed certain aspects of FT596, the cell product being tested in this study to Fate Therapeutics. The University of Minnesota may benefit financially if the product is marketed in the future. This interest has been reviewed and managed by the University of Minnesota in accordance with its conflict of interest policies. If you would like further information about this interest, please contact Jon Guden, Associate Director, Conflict of Interest Program, at jguden@umn.edu.

If you are an employee or relative of an employee of this research center, you are under no obligation to participate in this study. You/your family member may withdraw from the study at any time and for any reason, and neither you/your family member's decision to participate in the study, nor any decision on your/their part to withdraw, will have any effect on your/your family member's performance appraisal or employment at this clinical research center. You/your family member may refuse to participate, or

you/your family member may withdraw from the study at any time without penalty or anyone blaming you.

If you are a student of the researcher, you are under no obligation to participate in this study. You may withdraw from the study at any time and for any reason, and your decision to participate in the study, nor any decision on your part to withdraw, will have any effect on your performance or standing as a student. You may refuse to participate, or you may withdraw from the study at any time without any penalty.

Key Information About This Research Study

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

What is research?

Study doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Study doctors learn things by following the same plan with a number of subjects. You, as an individual, may or may not be helped by participating in a research study; however, your participation helps answer the research questions.
- The goal of routine (standard) treatment is to treat your medical condition. Standard treatments are available from any doctor.

Research and clinical care are often combined. One purpose of this consent document is to provide you clear information about the specific research activities of this study.

Why am I being asked to take part in this research study?

You are invited to take part in a research study because you have non-Hodgkin lymphoma and a transplant using your own blood cells is planned. Currently there is no standard of care treatment after transplant other than regular follow-ups and the use of the drug rituximab to prevent or reduce the chance of your cancer coming back after the transplant.

The purpose of this consent form is to help you decide if you want to participate in the research study.

You should not join this research study until all your questions are answered.

Things to know before deciding to take part in a research study:

- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this research study, your doctor will continue to treat you.
- You may change your mind and take back (withdraw) your consent at any time during your participation in the study without penalty or loss of any benefits to which you are otherwise entitled.
- Parts of this study involve standard medical care.

- Other parts of this study may involve experimental (investigational) therapy or procedures that are being tested for a certain condition or illness. An investigational therapy is one that has not been approved by the U.S. Food and Drug Administration (FDA) to treat the condition or illness for which it is being studied.
- After reading this consent form and speaking with the research staff, you should understand which parts of the study are investigational and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by Fate Therapeutics, Inc., which is the supplying the investigational cell therapy product FT596, the Institutional Review Board (IRB) reviewing this research study, as well as government agencies responsible for overseeing the conduct of the study, such as the FDA and health authorities from other countries.
- Your medical insurance may be billed for any standard medical care you receive during the research study. If your insurance company is billed, then it may have access to the research records. Insurance companies may not pay for treatment that is part of a research study.

If you take part in this research study, you will be asked to sign and date this consent form confirming that all of your questions about what the study is and what you will have to do during the study have been answered. By signing and dating, you are freely consenting to join this research study. You will be given a copy of your signed and dated consent form. If you decide not to take part in this research study, there may be other choices available to help treat your cancer. Ask the study doctor to discuss these choices with you.

Study Treatment Overview
Rituximab is a commonly used drug and can be given without being in a study (you may have received it in the past). It will be given at the usual dose as an intravenous infusion. It is given 2-3 days day before FT596 infusion to “prime” your immune system for the FT596 cells. It is given as an outpatient treatment, but if you are in the hospital, you will receive it as an inpatient treatment.

FT596 is given as an infusion in your vein (intravenous). Depending on the dose level to which you are assigned, you may receive 1 or more bags per dose. Each bag should take approximately 15 minutes to infuse. The process is similar to a blood transfusion. You will be given acetaminophen (Tylenol®) and diphenhydramine (Benadryl®) before and a few hours after the FT596 to help prevent any unwanted reactions to the infusion.

Why is this research being done?
FT596 is produced by growing cells that come from a live, healthy human donor. The donor cells are treated in a laboratory with a process that turns them into a type of cell called an induced pluripotent stem cell, which means that these cells can be turned into any type of human cell. In this case, the cells are turned into Natural killer (NK) cells

which are a specific type of lymphocyte. Once prepared, they are then frozen and shipped to your study doctor's office.

FT596 is different from the NK cells that are already in your body because FT596 has been changed through a process known as cell engineering. This type of cell engineering uses viruses to change the coded building blocks of cells, known as DNA, so the changed cells will work differently than they otherwise would. The viruses used for this engineering are unlikely to cause any infections in humans. To engineer FT596, three proteins (described below) were added to the cells.

- Chimeric antigen receptor (also called a CAR): this protein recognizes another protein called CD19, which is found on lymphoma cells, leukemia cells, and normal B-cells. FT596 has been engineered to bind to the cancer cells containing CD19; when the NK cells activate after being bound to a cancer cell, the NK cells will then kill the cancer cell.
- hnCD16: this protein will bind to monoclonal antibodies, which are a type of medication commonly given to people with your kind of cancer.
- IL-15/IL-15 receptor complex: this protein is intended to help the NK cells stay alive.

As this is one of the first in humans study of FT596 in this population, this study is being done in 2 parts (components), each with its own purpose, although the tests evaluations and follow-up schedule are the same for both.

Component 1 – FT596 given 30 days after transplant: In this part all subjects receive a single dose of rituximab followed 2-3 days later by a single infusion of FT596. Study treatment is given as an outpatient. Up to 3 dose levels of FT596 will be tested. **The purpose of Component 1 is to determine which dose level of FT596 is safe.**

Component 2 – FT596 given 7 days after transplant: In this part all subjects receive a single dose of rituximab followed 2-3 days later by a single infusion of FT596. Two dose levels will be tested in this component (one dose level below the dose level identified in Component 1 and the dose level identified in Component 1. Study treatment may be given as an outpatient, but will be given in the hospital for subjects still in the hospital after their transplant. **The purpose of Component 2 is to determine if giving FT596 shortly after a transplant is safe.**

You will be told which component of the study is enrolling and dose level of FT596 you will receive.

How long will I be in this study?
A single course of study treatment is given, either around 30 days after your transplant or around 7 days after your transplant. After the FT596 infusion you will have at least weekly clinic visits for 4 weeks to assess for side effects and check your blood counts.

After the 4 weeks of frequent visits, follow-up for this study will match your standard of care 3 month, 6 month, and 12 month (1 year) follow-up visits after the transplant.

Routine information obtained from these visits (physical exam results, lab work, disease response) will be recorded in the study record.

Your direct participation in this research study is about 1 year from the transplant; however, as part of this study you must agree to take part in a long-term follow-up (LTFU) study. After your participation ends in this treatment study, follow-up will continue at least once a year either in person, or by mail or telephone for an update on your overall health and if you have any new diagnoses of immune related conditions (for example, rheumatoid arthritis), neurological changes or new cancers. You will receive a separate consent form for the LTFU study.

What will I need to do to participate?
After you hear about the study, read through the consent and have your questions answered, you will be asked to sign and date this consent form if you are interested in the study. By signing and dating this consent, you are giving permission for the study staff to review your medical record to determine if you qualify for the study.

More detailed information about the study procedures can be found under **"What happens if I say yes, I want to be in this research?"**

Is there any way that being in this study could be bad for me?
Risks associated with FT-596 are based on experience with other NK cell products and may include:

Infusion Related Reaction is a potential risk of both rituximab and FT596 during the infusion or shortly after. This reaction could be mild (skin irritation/rash) to life-threatening (difficulty breathing/swelling of the face and throat). Medications are given before and after each infusion to lessen the risk of an allergic reaction. If a reaction occurs, the symptoms are treated with the appropriate medications.

Cytokine release syndrome (CRS) is a serious systemic (whole body) inflammation response. CRS is seen with other types of cell therapies, but is not typically seen with NK cell therapies. Signs of CRS include fever, nausea, headache, rash, rapid heartbeat, low blood pressure, and trouble breathing. Most subjects who develop CRS have a mild reaction, but sometimes, the reaction may be severe or life threatening. CRS is treated with supportive care and steroids.

More detailed information about the risks of this study can be found under **"What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)" and in the "What happens to the information collected for the research?" section.**

Will being in this study help me in any way?
If you agree to take part in this study, there may or may not be direct medical benefit to you. The information learned from this study may benefit other patients who are at an increased risk of relapse after a transplant.

What happens if I do not want to be in this research?
You do not have to participate in this research. Giving FT596 is an extra investigational option after transplant. Regardless of whether or not you take part in this study, you will receive the usual care after an autologous transplant of regular follow-up visits with or without rituximab given every few months. It is your decision.

Detailed Information About This Research Study
The following is more detailed information about this study in addition to the information listed above.

How many people will be enrolled in this study?
This is study will enroll subjects through the University of Minnesota and one other Midwestern Cancer Center with about half of the enrollment occurring at each site.

Component 1: It is expected 12 subjects are needed to determine a safe dose of FT596 at 30 days after transplant.

Component 2: It is expected 12 subjects are needed to determine a safe dose of FT596 at 7 days after transplant.

What happens if I say "*Yes, I want to be in this research*"?
Participation in the study will include:

- **Screening Period:** A screening period before you begin the transplant procedures. This study has very few requirements for taking part in it and will use the results of tests and evaluations done before the transplant. The main requirement for this study is that you are undergoing an autologous transplant and your disease has some features that may put you at a higher risk of relapse (your disease returning after the transplant). At this time, if you are interested in taking part in the study, you will be asked to sign and date this treatment consent (and the long-term follow-up consent form).
  The screening period will include tests to check for previous exposure to immunodeficiency virus (HIV), hepatitis B, and hepatitis C. If required by state law, the study doctor or study staff may report a positive test result to the local health department.
- **Confirmation of Study Participation:** After the transplant, it will be confirmed that taking part in the study is still felt to be safe and that you are still interested in taking part.
- **Study Treatment Period:** The study treatment period for this study depends are which part of the study you are enrolled in. This is explained in more detail below. Everyone receives a dose of rituximab followed 2 to 3 days later by an infusion of FT596 cells. A final study treatment visit occurs approximately 4 weeks (28 days) after receiving FT596.
- **Follow-up Period:** Follow-up visits with your study doctor on a regularly scheduled basis will be done as part of your post-transplant care. This study has a follow-up period 1 year after the transplant and whenever possible, follow-up

visits for this study will be at the same time as routine post-transplant follow-up visits.

- **Long-Term Follow-Up:** Because FT596 is a genetically modified cell product, follow-up for up to 15 years is required by the Food and Drug Administration. When you complete the follow-up directly related to this treatment study at 1 year, you will be "transferred" to a separate long-term follow-up study. You are receiving a separate consent explaining the once yearly follow-up, either in person or by mail, telephone call or other means.

Study Treatment Overview:
Rituximab is a commonly used drug and can be given without being in a study (you have probably received it in the past). It will be given at the usual dose as an intravenous infusion. It is given 2-3 days day before the FT596 infusion to "prime" your immune system for the FT596 cells. It is given as an outpatient treatment, but if you are in the hospital, you will receive it as an inpatient treatment.

FT596 is given as an infusion in your vein (intravenous). Depending on the dose level to which you are assigned, you may receive 1 or 3 bags. Each bag should take approximately 15 minutes to infuse. The process is similar to a blood transfusion. At certain points before and after you receive FT596, you will be given acetaminophen (Tylenol®) and diphenhydramine (Benadryl®) to help prevent any unwanted reactions to the infusion.

Study Treatment Plan Assignment:
After the transplant, it will be confirmed that taking part in the study is felt to be safe and that you are still interested in taking part.

Everyone in this study receives 1 dose rituximab followed 2-3 days later by 1 dose of FT596 as described above. The timing in relation to the transplant and the dose of FT596 is what varies.

The dose levels of FT596 are based on other ongoing research studies. Enrollment will be staggered such that one subject will be treated with FT596 and then a period of time must pass before the next subject is treated. This is to make sure there are no late side effects from the FT596

In **Component 1**, FT596 is given 30 days after the transplant.

Up to 3 dose levels of FT596 will be tested using a standard statistical design called 3+3. Each dose level will enroll 3 subjects until either Dose Level 3 is reached or there is unacceptable toxicity. At the top dose level, 3 more subjects are treated to gain additional safety information. If all 3 dose levels are tested without any unacceptable side effect a total of 12 subjects would be treated (3+3+6).

<u>If at any time an unacceptable side effect occurs,</u> additional subjects (up to 6) would be enrolled at the same dose plan to further evaluate the side effects to determine if it is

specific to one subject or if unacceptable side effects occur or other subjects. If no other side effects are seen and there are dose levels that have not been tested, enrollment may continue; however, in a future, 6 subjects would be treated at each dose level. As many as 18 subjects could be treated if 6 subjects need to be treated at each of the 3 dose levels (6+6+6).

The goal of Component 1 is to identify a safe dose level of FT596 for further testing.

In **Component 2,** FT596 is given 7 days after the transplant.

Component 2 tests two dose levels of FT596 based on what is learned in Component 1. It uses a different statistical plan call CRM. The first 3 subjects are treated at one dose level below the dose level identified in Component 1. For example, if Dose Level 3 is identified as the safe dose for Component 1, the 1st 3 subjects will receive FT596 at Dose Level 2. If no unacceptable side effects occur, the next 3 subjects are treated at the Component 1 dose (Dose Level 3 in the example). Subjects continue to be enrolled in groups of 3 at the most appropriate of the two dose levels until 6 subjects in a row are treated at Dose Level 3 or 18 subjects total are treated.

The goal of Component 2 is to determine if giving FT596 shortly after a transplant is safe.

Study Related Sample Collection (Research Related):
Because this is a research study, you will have research blood samples taken at the time you sign and date this consent (before you receive the transplant chemotherapy, before rituximab, before and after FT596 and up to 6 times over the next 4 weeks. In addition, blood for research will be collected at the standard of care follow-up visits after transplant at 3, 6 and 12 months. Approximately 5 tablespoons of blood will be collected at each time point. The blood samples will be collected at the time you are having blood work for your medical care except for a small sample (about 2 teaspoons) collected about 30 minutes after the FT596 infusion.

Blood from the research samples will be tested and analyzed to look at your immune system and the effects of FT596. The testing may include testing using genetic markers to see how much and how long FT596 is present in your blood. This research will a better understanding of how FT596 works. If there are tests that cannot be done at the study site, blood may be sent to outside labs, including Fate Therapeutic labs. Any samples leaving the study site will not contain information that could directly identify you.

If any blood left over from the collections described above, the extra blood may be stored for additional future research testing. This may include further tests about how FT596 works against cancer, or it may include tests about other cancer treatment or prevention methods. This testing may include future genetic testing.

Information obtained from testing the samples will be used only for purposes of research and development. None of the research-related testing results will affect your

care or your participation in this study. The results will not be placed in your medical record and will not be given to your insurance company or employer unless required by law. Neither you nor your health insurance provider will be charged for the cost of research sample processing, storage or testing. If the results from this study are published in a medical journal or presented at a scientific meeting, you will not be identified.

Genome Testing and Handling of Genetic Information

Biomarkers are substances in your body that may indicate something abnormal is happening in your body. Biomarkers may be tested as part of this study, including possible analysis of your genome (DNA).

Your blood and/or your tumor tissue samples may be tested to find about possible mutations (permanent alterations) and other possible changes to your genome. Testing will not be done to determine whether any mutations are inherited.

Studying the blood and tumor tissue samples from a large number of people may help researchers learn more about new treatments, cancer biology, and how mutations affect a person's response to treatment. The genetic test results are not intended to be used to guide you or your doctors in making any health care decisions. Research performed on these samples may benefit other patients with cancer similar to yours. There are no plans to return the results of this research to you.

The Genetic Information Nondiscrimination Act of 2008 generally makes it illegal in the United States for health insurance companies, group health plans, and most employers to discriminate against you on the basis of your genetic information. The law generally will protect you in the following ways:

- Health insurance companies and group health plans cannot request your genetic information from this research;
- Health insurance companies and group health plans cannot use your genetic information when making decisions regarding your eligibility or premiums; and
- Employers with 15 or more employees cannot use your genetic information from this research when setting the terms of your employment.

This United States federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

New findings

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

What happens if I say "Yes", but I change my mind later?

If you take part in this research study, and want to leave, you should let a member of the research staff or your doctor know. Your choice not to be in this study will not negatively affect your right to any present or future medical care. If you decide to leave the study before the End of Study Treatment visit 4 weeks (28 days) after the FT596

dose, you are asked to maintain contact with your study doctor in case of side effects. Regardless, it will be recommended that you continue the routine post-transplant follow-up.

If you stop being in the research, information about you that has already been collected may not be removed from the study database.

The study doctor or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

You may experience all, some, or none of the side effects described below. If you do experience any of them, they may vary in severity. The severity may be mild, moderate, or severe, up to and including death. You may experience side effects that are not expected and side effects may happen long after you receive FT596.

This is one of the first time that FT596 has been given to people, and therefore the risks are not known.

<u>Risks Related to FT596</u>

- **Infusion-related or allergic reaction**
  During the FT596 infusion or shortly after there is a risk of an infusion related reaction. This reaction may be mild (skin irritation/rash) to life-threatening (difficulty breathing/swelling of the face and throat). To lessen the risk of a reaction you will receive acetaminophen (Tylenol) and diphenhydramine (Benadryl) before and a few hours after the cell infusion. If an infusion reaction occurs, you will receive the appropriate medical care.
- **Cytokine release syndrome**
  Cytokine release syndrome (also called CRS) is an inflammatory response your body may experience with therapies designed to stimulate your immune system. CRS symptoms are usually mild to moderate, and include:
  - Fever
  - Nausea
  - Chills
  - Decreased blood pressure
  - Increased heart rate
  - Weakness
  - Headache
  - Rash
  - Scratchy throat

  - Difficulty breathing

  However, in rare instances, subjects can develop severe, even potentially life-threatening symptoms of CRS.
- **Loss of engraftment or failure to engraft (blood count recovery after transplant)**
  It is not known if giving FT596 before blood counts have recovered (engrafted) will affect blood count recovery after transplant. This is one of things this study is looking at. To be eligible for Component 1 (Day 30 FT596) blood count recovery must have occurred. Subjects receiving FT596 around Day 7 after transplant (Component 2) blood count recovery is not required.
- **Effects on the nervous system**
  Although this has not been a common risk with other NK cell therapies, treatment with cell therapies may result in side effects involving the brain and other parts of the nervous system. Effects observed with other cell therapies include confusion, delirium, and sometimes seizures and swelling of the brain that could lead to death.
- **DMSO and albumin related risks**
  FT596 is stored in a solution containing dimethyl sulfoxide (DMSO) and human albumin. DMSO may cause side effects like:
  - Coughing
  - Flushing
  - Rash
  - Chest tightness
  - Wheezing
  - Nausea
  - Vomiting
  - High or low blood pressure

Because of the small volume of the cell product, a reaction is not expected. You will receive intravenous (IV) fluid before and after the FT596 to reduce this risk.

- Allergic reactions may occur with human albumin. Symptoms could include:
  - Fever
  - Chills
  - Rash
  - Nausea
  - Vomiting
  - Fast heart rate
  - Low blood pressure
- **Increased risk of infection**
  Since FT596 is a cell therapy of human origin, there is a risk that you could receive infectious agents such as viruses, and/or other non-infectious agents, which may also cause side effects. FT596 has been extensively tested to reduce the risk of disease infection. However, these measures do not completely eliminate this risk. For some infectious agents, there are no routine tests to predict or prevent their presence.

- **Tumor lysis syndrome**
  Tumor lysis syndrome (also called TLS) can happen when cancer cells have broken down and pieces of those cells enter the bloodstream. Because of the transplant, there should be no or very few cancer cells in your body. TLS is not expected in this study. Symptoms may include weakness, low blood pressure, muscle cramps, and decreased urination. TLS can lead to kidney damage and/or other organ damage. Many factors can contribute to TLS, including the type of cancer you have, as well as what kind of treatments you have already had for your cancer. Let your study doctor know immediately if you are unable to urinate.

Risks of Rituximab

The risks of rituximab are well known, although it is not known if they will be different when rituximab is given before FT596. The 2-3 day delay between the rituximab and FT596 is to ensure there are no ongoing toxicities from the rituximab before giving FT596.

You may have received or will receive additional doses of rituximab outside of the single dose given in this study. Some of the risks refers to first infusion and others to 2nd or later which is based on your personal history of rituximab infusions. A summary is below:

Rituximab		
common	**less common**	**rare, but may be serious**
• mild allergic reaction with first infusion (may include fever, headache, chills, itching, hives, nausea, shortness of breath)	• allergic reaction with second and later infusions (same symptoms as under common) • low white blood cell count with increased risk of infection • cough • rash, itching • nausea • vomiting • diarrhea • muscle aches • runny nose • sinus infection	• serious allergic reaction, with hives, trouble breathing, tightness in the chest or throat, heart attack, or shock • serious skin reaction • kidney damage • low platelet count with increased risk of bleeding • blockage or hole in the bowel, with abdominal (belly) pain • low red blood cell count (anemia) with tiredness and weakness • death due to allergic reaction, infection, lung damage, tumor lysis syndrome, serious skin rash, bowel obstruction, liver failure from reactivated hepatitis b, and other causes

Other study risks may include:

- Blood Draws: you may feel pain and have minor bruising or bleeding at the needle site. There is a small chance of infection, and sometimes people feel faint or lightheaded when their blood is drawn.
- Risks of Genetic Research - The risks to you and your family from genetic research on the blood samples are very low, as the testing is on the abnormal cells, not your family genetics. The unique subject code assigned at study enrollment is used instead of your name or other identifying information making it difficult for anyone looking at the sample to know it belongs to you. Testing is done in batches (more than 1 subject at a time) and no research results will be placed in your medical record.
- Because this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality will occur. There are procedures in place to lessen the possibility of this happening (see "*What happens to the information collected for the research, including my health information?*" section below).

What do I need to know about reproductive health and/or sexual activity if I am in this study?

The effect of FT596 on an unborn baby or on sperm are not known. However, in this study all subjects receive rituximab which the effects on conception are better known and requires a minimum of 12 months of pregnancy prevention in both women and men.

Women who are pregnant are not eligible to take part in this study.

Females: Women of child-bearing potential must use a highly effective form of contraception from enrollment until at least 12 months after the final dose of rituximab.

Males: Must be sterile (biologically or surgically) or use a highly effective method of contraception from enrollment until at least 12 months after the final dose of rituximab.

According to the World Health Organization and the United States Center for Disease Control and Prevention, the most effective forms of birth control include complete abstinence, surgical sterilization (both male and female), intrauterine devices (IUDs), and the contraceptive implant. The next most effective forms of birth control include injectables, oral contraceptive pills, the contraceptive ring, or the contraceptive patch. Acceptable, but least effective, methods of birth control include male condoms (with or without spermicide) and female condoms.

If you or a female partner of a male subject become pregnant within 4 months after the last dose of FT596, it is important that you notify the study doctor or another research team member; however, pregnancy must not occur within 12 months after the last dose rituximab.

Will it cost me anything to participate in this research study?
FT596 is provided at no cost by Fate Therapeutics for the purpose of this study. The cost of processing and testing any samples collected for research is paid for by study funds.

Rituximab is also is known by its brand names of Rituxan, Truxima, and Ruxience. Rituxan was the original biologic form of rituximab to receive FDA approval. Truxima and Ruxience are FDA approved biosimilars. Drugs have generic versions, biologics have biosimilars. Biosimilars are made from the same types of natural sources, given in the same way, have the same treatment benefits, and same potential side effects. A prior authorization will be obtained from your health insurance for rituximab. Often, an insurance only will approve a biosimilar version as generally it is less expensive. This study permits use of whichever version of rituximab your health insurance approves.

You and/or your insurance company will be billed for any standard medical care given during this research study. This means your insurance company will be billed for the rituximab, hospitalization, outpatient clinic visits, routine medical care, all lab tests done for standard safety assessment, and assessments that are done for your medical care. You will be responsible for any copays your insurance normally issues for these visits/procedures.

Compensation For Participation
You will not receive any monetary compensation for your participation in this study.

What happens to the information collected for the research, including my health information?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible but participating in research may involve a loss of privacy and has a potential for breach of confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

Overview

If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research. If you sign and date this Consent Form, you are giving permission to use and share your health information for these purposes

and you are giving permission to any health care providers who are treating you to share your medical records with us.

What health information will be made available?
Health information about you to be used and shared for the research includes those items checked by the research team below:

☒ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, electroencephalography (EEG), electrocardiogram (ECG), and echocardiogram ECHO reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form.

What about more sensitive health information?
Some health information is so sensitive that it requires your specific permission. If this research study requires any of this sensitive information, the boxes below will be marked and you will be asked to initial to permit this information to be made available to the research team to use and share as described in this Consent Form.

☐ My drug & alcohol abuse, diagnosis & treatment records _____ (initial)
☒ My HIV/AIDS testing records _____ (initial)
☒ My genetic testing records _____ (initial)
☐ My mental health diagnosis/treatment records ____ (initial)
☐ My sickle cell anemia records _____ (initial)

Who will access and use my health information?
If you agree to participate in this study, your information will be shared with:

- The University of Minnesota research team and any institutions or individuals collaborating on the research with us;

- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)), individuals involved in processing any compensation you may receive for your participation, and others);
- The research sponsor(s), any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research;
- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as U.S. government agencies like the Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries); and
- Advarra IRB, the independent external Institutional Review Board that is responsible for the review of this study.

How will my information be used in publications and presentations?
Your health data will be used to conduct and oversee the research. We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, social security number (SSN) and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

Optional Consent for Future Use of Identifiable Data or Specimens
At the completion of this research study, we would like to store and be able to use and share your identifiable research related samples and/or health information with researchers at the study site or affiliated hospitals for other research related to the immune system and/or cancer. Any research that involves identifiable information will be reviewed by an Institutional Review Board (IRB), which is the committee that provides ethical and regulatory

oversight of research, prior to use. Because these specimens and/or health information are identifiable, we are asking your permission to store, use and share these for other research.

We may not ask for your consent before using or sharing your identifiable specimens or data. You will not receive any results or financial benefit from the future research done on your specimens or data. We may share your identifiable specimens or data with outside researchers who will use them for future research. Samples are labelled with your unique study code assigned at study enrollment and information such as the date of collection/study day that can be linked back to your health information through a master study list.

If you leave the study, you can ask to have the data collected about you removed or the samples destroyed. You can also ask us to remove information that identifies you from the data or samples. This may not be possible if your samples and data have already been shared.

Please indicate whether you will allow the identifiable research related samples and/or health information to be used for future research by putting your initials next to one of the following choices:

_____ (initials) NO, my identifiable research related samples and/or health information may not be used for future research. They may be used for this study only.

_____ (initials) YES, my identifiable research related samples and/or health information may be used for other future research studies

Do I have to sign and date this authorization and give my permission to make my information, including my health information, available for use and sharing?

No, you do not have to sign and date this authorization. But if you do not sign and date it, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing and dating this authorization.

Does my permission for making my health information available for use and sharing ever expire?

No, there is no expiration date. In California and any other state that requires an expiration date, the Authorization will expire 50 years after you sign and date this authorization document.

May I cancel my permission for making my health information available for use and sharing?

Yes. You may cancel your permission at any time by writing to the study doctor at the address on the first page of this form. If you cancel your permission, you will no longer be in the research study. You may also want to ask someone on the research team in canceling will affect any research related treatment. If you cancel your permission, any health information about you that was already used and shared may continue to be used and shared for the research study and any optional elements of the study to which you agree in this authorization.

What happens to my health information after it is shared with others?

When we share your information with others as described in this authorization, privacy laws may no longer protect your information and there may be further sharing of your information.

Will I be able to look at my records?

It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____ _____

Signature of Subject Date

_____

Printed Name of Subject

WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ

The study subject has indicated that he/she is unable to read. This Authorization document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness Date

What will be done with my data and specimens when this study is over?

We will use and may share data and/or specimens for future research. They may be shared with researchers/institutions outside of the study site. This could include for profit companies. We will not ask for your consent before using or sharing them. We will remove identifiers from your data and/or specimens, which means that nobody who works with them for future research will know who you are. Therefore, you will not receive any results or financial benefit from future research done on your specimens or data. No results from research related testing will be placed in your medical record.

Research samples may be sent to an outside laboratory for testing (including to Fate Therapeutics) that cannot be routinely performed at the study site. No information to directly identify you will be provided on these samples.

Will I receive research test results?

No, individual tests results will not be shared with subjects. Research related testing is not done in real-time like lab work for medical care. Instead the samples are stored frozen and tested in batches at a future date. If the research with your identifiable information or samples gives results that do have meaning for your health, the investigators will contact you to let you know what they have found.

Whom to contact about this study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact:

- By mail: Study Subject Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the number when contacting the Study Subject Adviser: Pro00045966.

To share feedback privately with the University of Minnesota Human Research Protection Program (HRPP) about your research experience, call the Research Participants' Advocate Line at 612-625-1650 or go to https://research.umn.edu/units/hrpp/research-participants/questions-concerns . You are encouraged to contact the HRPP 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.

The University of Minnesota HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous. If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the University of Minnesota HRPP.

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

Will I have a chance to provide feedback after the study is over?
You may be asked to complete a survey that asks about your experience as a research subject. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team at the contact information located on page 1 of this form.

What happens if I am injured while participating in this research?
In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury, let the study staff know right away. By signing and dating this document, you will not lose any of your legal rights or release anyone involved in the research from responsibility for mistakes.

Optional Storing of Leftover Samples for Future Research:
Once the research associated with this study there may be some leftover blood and cells from the samples collected for research purposes. With your permission we would like to store them for up to 15 years after the study ends for future analysis as new things are learned about the immune system and cancer. Leftover samples may be sent to labs outside of the study site if specialized testing cannot be performed locally. There is no cost to you or your insurance company for long-term storage. If you agree to storage now and later change your mind, you may contact a member of the study team and request that any remaining identifiable samples be destroyed.

Use of Identifiable Research Related Samples and/or Health Information
Please indicate whether you will allow the identifiable research related samples and/or health information to be used for future research by putting your initials next to one of the following choices as you indicated on page 17 of this document:

_____ (initials) NO, my identifiable research related samples and/or health information may not be used for future research. They may be used for this study only.
_____ (initials) YES, my identifiable research related samples and/or health information may be used for other future research studies

Signature Block for Capable Adult:

Your signature documents your permission to take part in this research. You will be provided with a copy of this signed and dated document.

_____ _____
Signature of Subject Date

_____
Printed Name of Subject

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

WITNESS SIGNATURE FOR SUBJECTS WHO CANNOT READ

The study subject has indicated that he/she is unable to read. The consent document has been read to the subject by a member of the study staff, discussed with the subject by a member of the study staff, and the subject has been given an opportunity to ask questions of the study staff.

_____

Printed Name of Impartial Witness

_____ _____

Signature of Impartial Witness Date