

Informed Consent Coversheet

Official Study Title:	ADMINISTRATION OF MOST CLOSELY MATCHED THIRD PARTY RAPIDLY GENERATED LMP, BARF1 AND EBMA1 SPECIFIC CYTOTOXIC T-LYMPHOCYTES TO PATIENTS WITH EBV-POSITIVE LYMPHOMA AND OTHER EBV-POSITIVE MALIGNANCIES (MABEL)
NCT number	NCT02287311
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CONSENT FORM
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals
TREATMENT CONSENT

HIPAA Compliant

H-35253- MABEL: ADMINISTRATION OF MOST CLOSELY MATCHED THIRD PARTY RAPIDLY GENERATED LMP, BARF1 AND EBNA1 SPECIFIC CYTOTOXIC T-LYMPHOCYTES TO PATIENTS WITH EBV-POSITIVE LYMPHOMA AND OTHER EBV-POSITIVE MALIGNANCIES

Background

In this document "you" signifies either you or your child. Please read this information and feel free to ask any questions before you agree to take part in this study.

You have a type of malignancy (cancer) or lymph gland disease associated with a virus called Epstein Barr Virus (EBV) which has come back, is at risk of coming back, or has not gone away after standard treatments. We are asking you to volunteer to be in a research study using special immune system cells called LMP, BARF-1 and EBNA1- specific cytotoxic T lymphocytes (referred to as MABEL CTLs throughout the rest of the consent form).

Some patients with Lymphoma (such as Hodgkin (HD) or non-Hodgkin Lymphoma (NHL)), T/NK-lymphoproliferative disease, severe chronic active Epstein Barr Virus (CAEBV), or solid tumors such as nasopharyngeal carcinoma (NPC), smooth muscle tumors, and leiomyosarcomas show signs of a virus called EBV before or at the time of their diagnosis. EBV causes mononucleosis or glandular fever ("mono" or the "kissing disease"). EBV is found in the cancer cells of up to half the patients with HD and NHL, suggesting that it may play a role in causing Lymphoma. The cancer cells (in lymphoma) and some immune system cells (in CAEBV) infected by EBV are able to hide from the body's immune system and escape destruction. EBV is also found in the majority of NPC and smooth muscle tumors, and some leiomyosarcomas. We want to see if special white blood cells (MABEL CTLs) that have been trained to kill EBV infected cells can survive in your blood and affect the tumor.

We have used therapy like this for cancer that occurs after bone marrow or solid organ transplant called post transplant lymphoma, as well as in a few patients with NPC, smooth muscle tumors, or leiomyosarcomas. In these type of cancers the tumor cells have 9 proteins made by EBV on their surface. We grew T cells in the lab that recognized all 9 proteins and were able to successfully prevent and treat post transplant lymphoma. However, in HD and NHL, T/NK-lymphoproliferative disease, and CAEBV, the tumor cells and B cells only express 4 EBV proteins. In a previous study, we made T cells that recognized all 9 proteins and gave them to patients with HD. Some patients had a partial response to this therapy but none had a complete response. We then did a study where we made T cells that recognized 2 EBV proteins (LMP1 and LMP-2) seen in patients with lymphoma, T/NK-lymphoproliferative disease, CAEBV, and NPC. The cells are called LMP-CTLs. We treated over 50 people on those studies and about 60% of the patients who had disease at the time they got the cells had responses including some complete responses.

In these previous studies, the EBV CTLs were generated from the blood of the patient, which was often difficult if the patient had recently received chemotherapy. Also, it took up to 1-2 months to make the cells, which is not practical when a patient needs more urgent treatment. To address these issues, MABEL CTLs were made in the lab in a simpler, faster, and safer way. The MABEL CTLs will still see the LMP proteins but also two other EBV proteins called EBNA-1 and BARF. To ensure these cells are available for patients in urgent clinical need, we have generated MABEL CTLs from the blood of healthy donors and created a bank of these cells, which are frozen until ready for use. We have previously successfully used frozen T cells from healthy donors to treat EBV lymphoma and virus infections and we

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now have improved our production method to make it faster.

In this study, we want to find out if we can use MABEL CTLs to treat HD, NHL, T/NK-lymphoproliferative disease, CAEBV, NPC, smooth muscle tumors, or leiomyosarcoma. We already searched the bank and found a MABEL CTL line that is a partial match with you.

MABEL CTLs are investigational and not approved by the Food and Drug Administration.

This research study is sponsored by Baylor College of Medicine. This research study is funded by Leukemia and Lymphoma Society and TESSA THERAPEUTICS PTE. LTD. The Principal Investigator RAYNE ROUCE for this study may receive royalties or money from patents related to the subject of the research

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.

Purpose

The purpose of this study is to find the largest safe dose of partially-matched MABEL CTLs chosen from the bank of frozen MABEL CTLs (created using this new manufacturing technique). We will learn what the side effects are and to see whether this therapy might help patients with Hodgkin disease or non-Hodgkin Lymphoma or EBV-associated T/NK-lymphoproliferative disease or CAEBV.

Procedures

The research will be conducted at the following location(s):

Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital.

Up to 42 subjects may be treated on this study.

Earlier, a healthy donor gave blood for us to make LMP/BARF1/EBNA-1 MABEL CTLs in the lab. We made the cells by first growing a special type of cells called activated T cells to stimulate the T cells. We then added specially produced mixtures of proteins that included the LMP, EBNA1 and BARF proteins. These were used to stimulate T cells. As the T cells grew, we added some of the healthy donor cells expressing these proteins to stimulate them. We also added a cell called K562 that has had new genes put inside it so it expresses proteins that stimulate the immune system to encourage the T cells to grow. K562 cells are cancer cells that have been treated with radiation so they cannot grow. This stimulation trained the MABEL CTLs to kill cells with EBV proteins on their surface. These cells were grown and frozen.

The MABEL CTLs will be thawed and infused into you over 1-10 minutes. You may be pretreated with Tylenol (acetaminophen) and Benadryl (diphenhydramine). Tylenol and Benadryl are given to prevent a possible allergic reaction to the infusion. Initially, two doses of MABEL CTLs will be given two weeks apart.

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Several studies suggest that the infused T cells need room to be able to proliferate and accomplish their functions and that this may not happen if there are too many other T cells in circulation. Because of that, if your level of circulating T cells is relatively high, you may require treatment with cyclophosphamide (Cytoxan) and fludarabine (chemotherapy drugs) before you receive MABEL CTLs. This will only occur if the study doctor feels you are well enough to receive these medications. These drugs will decrease the number of your own T cells before we infuse the MABEL CTLs. Although we do not expect any effect on your tumor with the dose that you will receive, this drug is part of many regimens that are used to treat lymphoma or leukemia. If you are already receiving chemotherapy, this may not be needed.

This is a dose escalation study. This means that at the beginning, patients will be started on the lowest dose (1 of 3 different levels) of MABEL CTLs. Once that dose schedule proves safe, the next group of patients will be started at a higher dose. This process will continue until all 3 dose levels are studied. If the side effects are too severe, the dose will be lowered or the MABEL CTLs infusions will be stopped.

You may receive a lower dose in the event that an insufficient number of cells are manufactured. If after your second infusion there is no change OR a reduction in the size of your disease on CT or MRI scan as assessed by a radiologist, you can receive additional doses of the MABEL CTLs if you wish (up to 6 times). Follow up testing will be collected just as it had from the first infusion. If your circulating T cells are relatively high prior to any additional dose of MABEL CTLs you may receive treatment with cyclophosphamide and fludarabine before the additional doses of CTLs.

In between the first and second T cell infusions and for 6 weeks after the last infusion, we ask that you not receive any other anti-cancer treatments such as radiation therapy or chemotherapy. If you do receive any other therapies in-between the first and second infusion of T cells, you will be taken off treatment and will not be able to receive the second infusion of T cells.

All of the treatments will be given by the Center for Cell and Gene Therapy at Texas Children's Hospital or Houston Methodist Hospital.

Medical tests before treatment:

Before being treated, you will receive a series of standard medical tests:

Physical exam

Blood tests to measure blood cells, kidney and liver function

Measurements of your tumor by routine imaging studies. We will use the imaging study that was used before to follow your tumor: Computer Tomogram (CT), Magnetic Resonance Imaging (MRI), or Positron Emission Tomography (PET/CT)

Pregnancy test for females who are able to have children

Medical tests during and after treatment:

You will receive standard medical tests when you are getting the infusions and after:

Blood tests to measure blood cells, kidney and liver function

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Imaging study 8 weeks after the 1st CTL infusion. If you receive additional doses you will also have an imaging study at 1 to 3 months after your final dose.

We will follow you after the injections. You will either be seen in the clinic or you will be contacted by research staff yearly for 5 years. To learn more about the way the T cells are working in your body, an extra 20-50 mL (4-10 teaspoons) of blood will be taken before each infusion and then at 1, 2 and 6 weeks and 3, 6, 9 and 12 months after the infusion (7 times). If you receive additional doses of MABEL CTLs you will have 20-50 ml (4-10 teaspoons) of blood drawn before each infusion and then at 1, 2 and 6 weeks after each infusion and then at 3, 6, 9 and 12 months after the last infusion. The blood may be drawn from your central line at the time of your regular blood tests. We will use this blood to see how long the MABEL CTLs last and to look at the immune response to your cancer.

One additional blood sample might be drawn 3 to 4 days after the infusion; this is optional. Please let your doctor know if it will be difficult for you to come in for this blood draw on Day 3 to 4.

These specimens and information about your circumstances may be used in other research being conducted in immune therapy. The specimens may be kept for a long time. Although there will be a record identifying under what circumstances these specimens were obtained, under all circumstances your identity will be kept confidential. There is a small risk for the loss of confidentiality. However, study personnel will make every effort to minimize this risk.

If you have a tumor biopsy at any time during the first year of your participation in this study, we will obtain a portion of that biopsy for research purposes.

In the event of death, we will request permission to perform an autopsy to learn more about the effects of the treatment on your disease.

Study Duration: You will be on study for approximately 5 years. If you receive additional doses of the MABEL CTLs as described above, you will be followed until 5 years after your last dose of MABEL CTLs.

As part of the study, we will collect information about you including your name, medical record number and date of birth. This information will be stored in a secure place and only study investigators will have access to it.

If you decide to withdraw at any time during the study both samples and data collected during your participation will be maintained.

Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital to use

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or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Specific information concerning psychiatry notes
- Demographic information (name, D.O.B., age, gender, race, etc.)
- Billing or financial records
- Photographs, videotapes, and/or audiotapes of you

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, TCH: Texas Children's Hospital, TMH: The Methodist Hospital, and LEUKEMIA & LYMPHOMA SOCIETY and their representatives.

Agents of the U.S. Food and Drug Administration may inspect the research records including your health information. Agents of regulatory agencies such as the U.S. Department of Health and Human Services will be permitted to inspect the research records including your health information.

A Data and Safety Monitoring Board will have access to the research records including your health information.

Use or Disclosure Required by Law

Your health information will be used or disclosed when required by law .

Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability and conducting public health surveillance, investigations or interventions.

Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research involves treatment. You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment. To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the

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study is complete. However, your health information that is necessary to your care will be provided to you or your physician. At the conclusion of the research and at your request, you generally will have access to your health information that Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital maintain in a designated record set, which means a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital to make decisions about individuals. Access to your health information in a designated record set is described in the Notice of Privacy Practices provided to you by representatives of the specific institution where you are being enrolled into this research study which are: Baylor College of Medicine, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, LEUKEMIA & LYMPHOMA SOCIETY and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, FDA, Baylor College of Medicine, Data and Safety Monitoring Board, TCH: Texas Children's Hospital, and TMH: The Methodist Hospital may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Rayne Rouce, 1102 Bates Street, Suite 1700, Houston, TX 77030.

This authorization does not have an expiration date. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts

Similar types of T cells have been given to over 100 patients to prevent lymphoma after transplant and to over 50 patients with Hodgkin or non Hodgkin lymphoma. Most patients had no side effects. In some patients with bulky disease, the cells have caused inflammation leading to fever and flu-like symptoms as well as swelling at the tumor site. This swelling could be potentially dangerous and even life threatening depending on the site.

There is also a risk that the cells could cross react with normal proteins in your body rather than the EBV proteins and cause damage to normal organs. We try to reduce this risk by checking the killing of the cells before we give them back to you.

As the T cells will be grown for several days after contact with the stimulator cells (K562 cells or healthy donor cells with the EBV proteins) it is possible that these cells could be injected with your T cells. K562

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cells are cancer cells. As such they could cause cancer. This is unlikely because we will test the T cells before we use them and we will also wash the cells several times so there should not be any protein remaining. However, we cannot completely exclude this possibility.

A small percentage of patients that receive this type of therapy develop a life threatening complication known as cytokine release syndrome (CRS). This complication causes high body temperature, increased heart rate, and low blood pressure. This complication can be life threatening, but you will be monitored carefully for development of this complication. There are treatments for this complication.

Side effects of lymphodepletion chemotherapy with cyclophosphamide and fludarabine :

Risks and side effects related to cyclophosphamide include :

Likely:

Loss of appetite, Nausea; Vomiting; Fewer white blood cells in the blood (A low number of white blood cells may make it easier to get infections); Hair loss; Decreased ability of the body to fight infection; Absence or decrease in the number of sperm which may be temporary or permanent which may decrease the ability to have children

Less likely:

Abnormal hormone function which may lower the level of salt in the blood; Abdominal pain; Diarrhea; Fewer red blood cells and platelets in the blood; A low number of red blood cells may make you feel tired and weak; A low number of platelets may cause you to bruise and bleed more easily; Bleeding and inflammation of the urinary bladder; Absence or decrease of monthly periods which may be temporary or permanent and which may decrease the ability to have children; Temporary blurred vision; Nasal stuffiness with IV infusions; Skin rash; Darkening of areas of the skin and finger nails; Slow healing of wounds; Infections.

Rare but serious:

Heart muscle damage which may occur with very high doses and which may be fatal; Abnormal heart rhythms; Damage and scarring of lung tissue which may make you short of breath; A new cancer or leukemia resulting from this treatment; Damage or scarring of urinary bladder tissue; Severe allergic reaction which can be life threatening with shortness of breath, low blood pressure, rapid heart rate, chills and fever ; Infertility which is the inability to have children.

Risks and side effects related to fludarabine include :

Likely (may happen in more than 20% of patients):

Low number of red blood cells (anemia); Low number of white blood cells; Low number of blood platelets; Feeling tired; Nausea (feeling sick to your stomach); Throwing up (vomiting); Weak immune system; Pneumonia (infection of the lungs); Infection; Bleeding; Pain; Electrolyte imbalance.

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Less likely (may happen in fewer than 20% of patients):

Diarrhea; Mouth sores; Skin rash; Fever; Swelling of hands and feet; Numbness and tingling in hands and/or feet; Loss of appetite.

Rare but serious (may happen in fewer than 2% of patients):

Changes in vision; Feeling nervous or anxious; Confusion; Cough; Difficulty breathing; Feeling weak; Severe brain injury which can lead to death; Kidney damage that could require dialysis; Coma; New (secondary) cancers

Other Risks

Acetaminophen (Tylenol): Rarely large doses or long term usage can cause liver damage, rash, itching, fever, lowered blood sugar. These side effects are unlikely at the doses being used for this study.

Benadryl: Drowsiness, dizziness, headache, irritability, stomach upset, vision changes (e.g., blurred vision), decreased coordination, or dry mouth/nose/throat may occur

Blood Draws: pain, bruising, lightheadedness, potential for infection.

Because of potential or unknown effects of the study on a fetus, if you are a woman of child-bearing potential, you must have a negative pregnancy test prior to entry into this study.

We will watch you very carefully for any side effects. If there are bad side effects, we will stop the treatment.

There may be unknown risks or discomforts involved. Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits

The benefits of participating in this study may be: It is possible that your immune system may begin to kill the EBV-infected cancer cells and B cells, making your disease go into remission or go away. Additionally your participation may help the investigators better understand how the immune system can fight EBV+ malignancies. This could benefit other patients with these diseases. However, you may receive no benefit from participating.

Alternatives

The following alternative procedures or treatments are available if you choose not to participate in this study: no further treatment, or other treatment with chemotherapy and radiation. Your doctor will discuss these other options with you. Additionally, the same alternatives are available if after participation in this research project you are not responding to the therapy.

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Subject Costs and Payments

You will not be charged for the manufacture or preparation of the MABEL CTL infusions nor will you be charged for the laboratory studies done to monitor how well these CTLs are working and to measure how long they stay in your body. You or your insurance company may be charged for some research related costs including the injection of the product. You will be charged for any tests or treatments that are being done as standard treatment for your disease.

You will not be paid for taking part in this study.

This institution does not plan to pay royalties to you if a commercial product is developed from blood or tissue obtained from you during this study.

Research Related Injury

If you are injured as part of your participation in this study, there are no plans to pay you.

Research personnel will try to reduce, control, and treat any complications from this research. If you are injured because of this study, you will receive medical care that you or your insurance will have to pay for just like any other medical care.

Women of Childbearing Potential

It is possible that the medicines used in this study could injure a fetus if you or your partner becomes pregnant while taking them. Because of the potential risks involved, you or your partner should not become pregnant while you are participating in this study.

If you are sexually active or become sexually active and can get pregnant or can get your partner pregnant, you must agree to use one of the following forms of birth control every time you have sex and for (6) months afterwards:

- * oral contraceptives ("the pill"),
- * intrauterine devices (IUDs),
- * contraceptive implants under the skin, or contraceptive injections,
- * condoms with foam.

Should you become pregnant while on this study, you must immediately notify the study personnel.

The investigator will assist you in finding appropriate medical care. The investigator also may ask to be allowed to continue getting information about your pregnancy. You can choose not to provide this information.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

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You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, RAYNE ROUCE, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: RAYNE HELEN ROUCE at 832-824-4716 or during the day or 832-826-0860 after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

The National Institutes of Health and the National Cancer Institute may have access to your records for research purposes. Coded information may be provided to the NIH/NCI such as Patient ID, Patient Zip code, Patient country code and Patient Birth date (month/year). However, in the event of an audit NIH/NCI might have access to more information that is part of your research record.

In addition, study data is sent to the company, Tessa Therapeutics, Ltd. They will not have access to any information that could identify you.

Financial Conflict of Interests: The following investigators were determined to have financial conflict based on their relationships with immuno-oncology companies that make cell-based immunotherapy products, which is the focus of this funded research:

-Dr. Heslop has relationships with these entities: Gilead Sciences, Inc (Scientific Advisor/Scientific Advisory Board), Kiadis Pharma (Scientific Advisor/Scientific Advisory Board, Stock Options), Marker Therapeutics, LLC (Equity), Novartis (Consulting, Advising), and Tessa Therapeutics PTE Ltd (Consulting, Advising)

-Dr. Brenner has relationships with these entities: Allogene (Income, Stock Options), Bellicum Pharmaceuticals (Intellectual Property Ownership), Bluebird Bio, Inc (Scientific Advisory Board), Kuur Therapeutics (Scientific Advisory Board), Marker Therapeutics, LLC (Equity), Memgen, LLC (Income), Tessa Therapeutics PTE Ltd (Income, Equity), Turnstone Biologics Ltd. (Income), and Walking Fish (Income, Stock Options)

-Dr. Rooney has relationships with these entities: Allogene (Income, Stock Options), Bellicum Pharmaceuticals (Intellectual Property Ownership), Bluebird Bio, Inc. (Scientific Advisory Board), Kuur

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Therapeutics (Scientific Advisory Board), Marker Therapeutics, LLC (Equity), Memgen, LLC (Income), Tessa Therapeutics PTE Ltd (Equity), Turnstone Biologics Ltd. (Income), and Walking Fish (Income, Stock Options)

-Bambi Grilley, BS, RPh, RAC, CIP, CCRC, CCRP owns a consulting company, QB Regulatory Consulting, LLC that develops, implements and conducts protocols for external sponsors.

-Dr. Leen has equity in Marker Therapeutics, LLC.

- Baylor College of Medicine (BCM) has a financial interest with Tessa Therapeutics PTE Ltd due to licensing agreements with the company.

ADULT ASSENT (as applicable)

If the person you represent is the one invited to take part in this study, you are signing to give your permission. Each adult who lacks the capacity to consent may agree to take part in a study at his or her own level of understanding. When you sign this, you also note that the person you legally represent understands and agrees to take part in this study according to his or her understanding.

Please print the person name you legally represent here _____.

If your child is the one invited to take part in this study you are signing to give your permission. Each child may agree to take part in a study at his or her own level of understanding. When you sign this you also note that your child understands and agrees to take part in this study according to his or her understanding.

Please print your child's name here _____

Patient Initials/ID _____ / _____

Protocol Version 10.0

HIPAA Compliant

CONSENT FORM
Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals
TREATMENT CONSENT

H-35253- MABEL: ADMINISTRATION OF MOST CLOSELY MATCHED THIRD PARTY RAPIDLY GENERATED LMP, BARF1 AND EBNA1 SPECIFIC CYTOTOXIC T-LYMPHOCYTES TO PATIENTS WITH EBV-POSITIVE LYMPHOMA AND OTHER EBV-POSITIVE MALIGNANCIES

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

_____ Subject	_____ Date
_____ Legally Authorized Representative Parent or Guardian	_____ Date
_____ Legally Authorized Representative - Adult	_____ Date
_____ Investigator or Designee Obtaining Consent	_____ Date
_____ Witness (if applicable)	_____ Date
_____ Translator (if applicable)	_____ Date

Patient Initials/ID _____ / _____

Protocol Version 10.0