EXAMPLE PATIENT EDUCATION SHEET FOR PARTICIPATING IN IMMUNE EFFECTOR CELL THERAPIES

Disclaimer: This example is just one of many potential examples of patient education material that can be provided to a patient. Institutions may choose to provide patient education in a different format depending on the institution's preferences, the patient's clinical situation, or the type of cellular therapy product.

The general expectation is that the immune effector cell (IEC) program has patient-oriented materials to inform participants of unique cell therapy processes they will undergo, expected toxicities, and the importance of close communication with IEC providers on specific symptoms that may put them in jeopardy of experiencing more serious complications. If this example is used, the program is responsible for updating it as new information becomes available.

What you should know about CAR T-cell Therapy

Chimeric antigen receptor (CAR) T-cell therapy

What is CAR T-cell therapy?

CAR T-cell therapy is a new treatment to fight some cancers. It involves using your body's own immune system to treat your cancer. Most treatments of this kind are currently only available in clinical trials, though a limited number of FDA-approved biologics are available for certain indications.

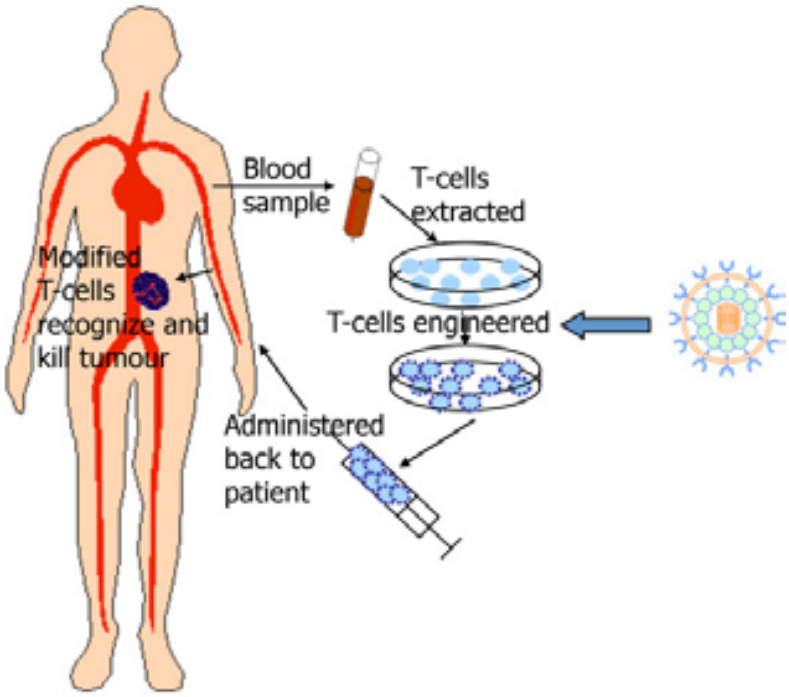
How it works

The immune system is made up of specific cells and organs that protect your body from organisms that cause infection, disease, and abnormal cancer cells. CAR T-cell therapy modifies your immune system activity to improve the body's own ability to fight certain cancers.

CAR T-cell therapy changes some of your body's T cells, which are collected from your own blood.

In a laboratory, your T cells will be reprogrammed to produce special receptors called **chimeric antigen receptors (CARs).** When these CARs are placed back into your body through an intravenous catheter, the receptors should help your T cells find and destroy cancer cells.

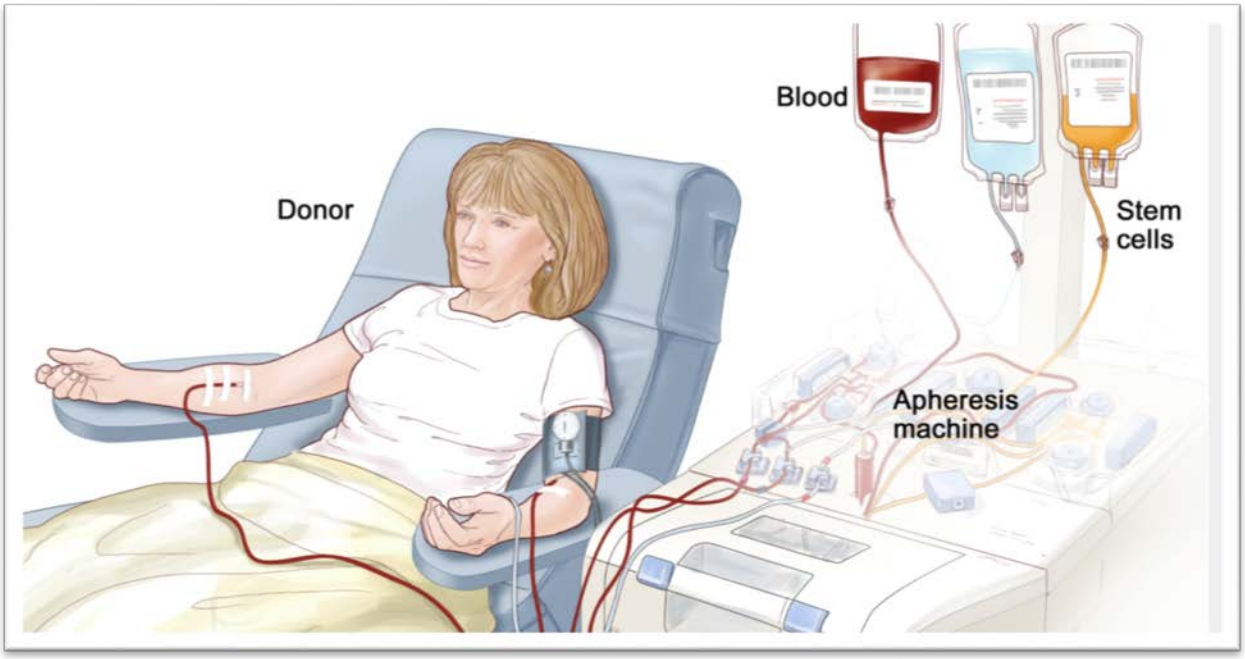
Throughout this process, careful measures are in place to ensure your safety and maintain high levels of quality.



Graphic used with permission from The Stiliyan Petrov Foundation (SPF), with reference to the Department of Haematology at the University College London, UK. **www.thestiliyanpetrovfoundation.com/cart-t-cell.html**

Steps needed before the actual treatment

To start the CAR T-cell therapy process, your care team will use an *apheresis machine* to collect your T cells. This machine removes some of your blood from a needle in one arm and, after separating out certain needed blood cell components, returns the blood into your other arm.



The apheresis procedure is done in one day, in a clinic setting at XXX institution.

After the needed blood cells are collected, they are genetically engineered, either at your medical center or in a special lab. The T cells receive genetic instructions to make the CAR protein and the lab produces enough of these cells for clinical use. The cells are then prepared for infusion back into your body. This process can take a few weeks. In the meantime, you may receive chemotherapy for your cancer.

The infusion of the CAR T cells

When your CAR T cells are ready and your care team recommends the start of treatment, you will be admitted to the hospital at XXX institution. Your CAR T cells will be infused back into your body in a process similar to a blood transfusion.

Your team of doctors and nurses will monitor you closely. You will get medications to help prevent and control side effects. Your response will depend on the cancer type, location, treatment doses, and your overall health. You will need to stay in the hospital for a few days or even several weeks, depending on your clinical situation and whether the risk for severe side effects is diminished.

Things that may occur during CAR T-cell infusion (or hours or days after)

- **Cytokine release syndrome**. In some patients, the immune system may become activated as the CAR T cells travel through the body. Substances called *cytokines* release into the system. This can make you feel like you have the flu, with a high fever and/or chills. Other symptoms that may occur include low blood pressure, difficulty breathing, or confusion. These symptoms can be mild or severe. Your team will monitor you frequently to help control these problems. You may need oxygen, intravenous fluids, and/or medicines (including steroids) to keep your fever down. In severe cases, you may receive medicines designed to stop the effect of the cytokines. Talk with your clinical team about the likelihood that you could have any of these symptoms.
- **Changes in neurologic status**. In some patients, the immune activation after CAR T-cell infusion may alter the brain and neurologic system temporarily. These changes can present as confusion, difficulty with talking or memory, or even in severe cases loss of consciousness. Your team will monitor you frequently and may give you special medications to help prevent or control these problems.

Symptoms that may occur days or even weeks after CAR T-cell infusion

- **B-Cell Aplasia**. B cells are a type of immune system cell. Some cancers also involve B cells, such as lymphoma. When CAR T cells are engineered to target B cells, there can be a very large drop in the number of those cells in the body. Because B cells are important to your immune system's ability to prevent infections, you may need to get a medicine through IV called *immune globulin* to help support your immune system after receiving CAR T cells.

- **Tumor Lysis Syndrome**. CAR T-cell therapy is designed to target <u>your</u> cancer cells. In some cases, this process may destroy a large amount of tumor. When these cancer cells die, the contents of the cells are released into your bloodstream. This can result in shifts of fluid and minerals, and/or kidney damage. Your team will have a specific treatment plan for you, if needed. This may include chemotherapy prior to T cell therapy, IV fluids, and or medicines to help the body clear these excess fluids and protect the kidneys.

After you leave the hospital

After you return home from the hospital, you should call your CAR T doctor if you have any symptoms of **cytokine release syndrome** (see above). If your symptoms are severe, go to the emergency room.

- The signs and symptoms of cytokine release syndrome can be very similar to those of acute infection (which can be life-threatening), so specific assessments and tests may be needed to ensure that you receive the appropriate care.

Your care team will give you more information about your CAR T-cell therapy. This will include more specific handouts and a card that you will be asked to carry with you at all times.

IMPORTANT REMINDER
If within the first 2-3 months after receiving CAR T-cells you need to visit any doctor (including the emergency room), be sure to let them know that you recently had CAR T cell therapy. Ask them to call your CAR T doctor and/or the number on your CAR T card.

The information in this document includes some, but not necessarily all, of the possible side effects of this therapy. The side effects listed in this teaching sheet may not be the same ones you experience. Your side effects may be different, depending on how often you receive treatment (your schedule) and how many cells you receive each time (your dosage). Side effects may also vary if you are taking other medications. Please speak with your doctor or nurse if you have questions about possible side effects you may experience. This document should not take the place of conversations with members of your health care team.

If you experience any significant change in your health during or after treatment, contact a member of your health care team right away.

THIS SPACE RESERVED FOR WRITTEN COMMENTS OR NOTES FOR THE PATIENT AND FAMILY: