## Overview

Protocols involving gene transfer are subject to additional institutional and regulatory requirements. This information sheet provides consent form guidance and recommended language for these studies. The language has been approved by the DFCI IRB. Study teams are encouraged to adhere to this guidance when drafting consent forms in order to avoid delays during IRB and Biosafety reviews.

## Template Consent Form Language for CAR T Cell Therapy Studies

*Please include the following language within the specified consent form sections, revising as needed for the particular study. Much of it is specific to CAR T-Cell therapy and will need to be altered for other types of studies.*

### B. Why is this research study being done?

*[XYZ]* is an investigational treatment that uses your own immune cells, called T cells, to try to kill your cancerous cells. T cells fight infections and can also kill cancer cells in some cases. Currently, your T cells are not able to kill your cancerous cells. In this study, some of your T cells will be removed from your blood, changed in a laboratory, and then given back to you by intravenous (IV) infusion. While in the laboratory, we will put new genetic material into your T cells. T cells that have genetic material added are called genetically changed T cells. If your genetically changed T cells recognize and attach to cancer cells, they may have the ability to become activated and kill them.

### D. What is involved in the research study?

**T Cell Collection Visit (Leukapheresis):**
In order to make the investigational genetically changed T cells, your white blood cells will be collected at the hospital by a process called leukapheresis. Leukapheresis requires having an intravenous (IV – in the vein) needle placed in each arm. Blood is taken from one arm, processed in a cell separator to remove the white blood cells, and the remaining blood components are returned to you through the other arm. You will receive a blood thinner (anticoagulant solution) which will allow us to collect your white blood cells without them sticking together.

During the leukapheresis procedure, the total volume of blood circulating through your body will pass through the leukapheresis machine 1-2 times. The process can take up to 4 hours.

There is a very small risk that we will not be able to collect enough cells to make your dose of investigational T cells. If this is the case, your study doctor will discuss with you the possibilities of getting the investigational T cells at a lower dose or undergoing a second leukapheresis procedure.

**Genetically Changing Your T Cells:**
Once your cells are collected, they will be sent to a laboratory. At the laboratory, genetic material is inserted into your cells using a virus called [insert type of virus: e.g., a lentivirus]. The virus is used like a transportation system for delivering the genetic material into your T cells (the virus is like a car and the genetic material is like a passenger). Viruses are used because they are very good at getting into T cells and inserting the new genetic material. The virus has been changed in the laboratory so that it is not likely to reproduce or cause an infection once it is in your body.

**Study Treatment Visit:**
The investigational T cells will be given to you through an intravenous (IV) infusion. The cells will be administered over approximately *[XYZ]* minutes. You may receive pre-medications such as Tylenol and Benadryl to help prevent a reaction to the infusion.

After receiving your investigational T cells, you will need to stay in the hospital for at least *[XYZ]* days so that we can monitor you closely. After you leave the hospital, you should remain within a 30 mile radius of the hospital until *[XYZ]* days after study treatment. This will ensure that any side effects you might experience can be promptly managed by your research doctor.

**Autopsy:**
*The IRB prefers that language about autopsy is not included in the consent as it is not a procedure that occurs as part of study participation and participants may find the language alarming and intrusive. Additionally, note that MA law does not allow participants to consent to their own autopsies.*
*If discussion of autopsy is required, only the following language will be approved by the IRB. It should be included at the end of Section D of the consent (after discussion of any follow up procedures).*

If you participate in this study and pass away, the research doctor may ask your family for permission to perform an autopsy. An autopsy may help researchers learn more about *[XYZ]*. Because the decision about performing an autopsy would be up to your family, we encourage you to advise them of your wishes. Your family would not be responsible for the costs of the autopsy.

## F. What are the risks or discomforts of the research study?

*Please be sure to include any additional risks of the viral vector used in the study, as well as any additional risks for the particular participant population.*

**Risks Associated with Genetically Changed T Cells:**

- There is a very small chance that the genetically changed T cells could cause healthy cells to become damaged which may lead to cancer (including blood cancer).
- *[Insert of a lentivirus is the viral vector:]* There is a very small risk that the virus used to change your T cells could change and grow once it has been given to your T-cells. This would be called a Replication Competent Lentivirus or "RCL". The risks from developing RCL are not known, but it is possible that RCL could lead to cancer. The risk is low because the viral vector has been changed to prevent RCL from happening. During the study, you will be tested regularly for RCL.
- *[Insert if a gamma-retrovirus is the viral vector:]* There is a very small risk that the virus used to change your T cells could change and grow once it has been given to your T-cells. This would be called a Replication Competent Retrovirus or "RCV". The risks from developing RCV are not known, but it is possible that RCV could lead to cancer. The risk is low because the viral vector has been changed to prevent RCV from happening. During the study, you will be tested regularly for RCV.
- *[Insert of a lentivirus is the viral vector:]* The virus used to change your T cells is related to the Human Immunodeficiency Virus (HIV), but it cannot infect you with HIV. You cannot get HIV from the genetically changed T cells. However, there is a chance that, as a result of receiving the T cells in this study, you may have false positive HIV tests in the future. If this happens, you would undergo more testing to confirm that you do not actually have HIV.
- *[If applicable:]* The virus used to change your T cells may be present in body fluids. If it is, it could be passed on to close contacts like an infection.

## References

*Informed Consent Guidance for Human Gene Transfer Trials subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, Office of Biotechnology Activities, Office of Science Policy, National Institutes of Health, April 2014.
http://osp.od.nih.gov/sites/default/files/resources/IC2013.pdf

*Guidance for Industry: Gene Therapy Clinical Trials – Observing Subjects for Delayed Adverse Events*, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research, November 2006.
http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/ucm078719.pdf