

Agreement for Freezing and Storage of Cellular Therapy Products

You need to read this form carefully. If there are words or parts of this document that you do not understand, ask your transplant provider or staff to explain any information that is not clear to you before signing.

Introduction:

Stem cells for your treatment and planned transplant require testing and storage. The Transplant & Cellular Therapy Program at _____ has a contract with Versiti Inc. to test, prepare, and store your cells or cells donated for your care. To maintain the life (viability) of the cells until they are needed, the Cellular Therapy Laboratory (CTL) at Versiti Michigan prepares the cells in a way that allows them to be frozen and stored at very cold temperature (at or below -240°F).

Purpose:

The purpose of this agreement is to inform you of the CTL policies on the freezing, storage, and disposal for cellular therapy products.

Cellular Therapy Product Transfer & Processing:

After the collection, your cells will be transported to Versiti Michigan for further processing. Many precautions are taken for safe handling of the cellular product during transport.

At the time of receipt of your cells at Versiti Michigan, a small amount of the cells is used for testing to ensure the number and condition of your cells is suitable for your upcoming transplant. All or a portion of the cells taken from you, or from your donor, are prepared for freezing. The CTL will prepare the cells according to lab procedures for freezing, and then the cells are mixed with chemicals that prevent injury to the cells during the freezing process. The cells will be divided into one or more bags, and slowly frozen to -96°F. The frozen bags are then transferred for storage into ultra cold freezers.

Every attempt is made by Versiti Michigan to maintain high standards for the processing and storage of your cells. The processing and freezing carries some risk of harm to the stem cells. Very rarely the processing may introduce bacteria or fungus in the bag. The risk for any contamination of the cells is monitored by microbial cultures prior to reinfusion. The cells are handled gently and are stored in protective metal canisters to reduce the chance of breakage during freezing. The freezers are continuously monitored and have alarms to make sure the stem cell products remain frozen. However, despite careful handling, cell loss may occur due to breakage or the life (viability) of the cells may be reduced.

Your provider will be notified if there is loss or damage to your collected cells during transport, processing, or storage. The transplant provider will decide if the cells are safe to use or should be discarded. You will be informed if this occurs, and your provider will discuss options available for your treatment.

Cellular Therapy Product Storage & Disposal:

Your cells will be frozen and stored for up to 10 years from the date of collection. Any remaining cells after your initial transplant may be available for future treatment. If, after 10 years, your transplant provider determines you no longer need the remainder of your cells or at the time of your death (whichever occurs first), the cells will be disposed. At the time of disposal, you have the choice to either allow Versiti Michigan to use your cells for quality testing, training purposes, or research, or for the cells to be properly discarded. If you desire your cells to remain in storage, they will need to be transferred to another facility. You must notify the CTL before the disposal date. You are responsible for their storage and any fees that apply.

Financial Risks:

If you choose to transfer your cells to another storage facility or treatment facility, additional fees may be applied for the transfer and storage at this new facility.

