

## New Cell Therapy Incubator launched

The new, state-of-the-art Cleveland Cord Blood Center Cell Therapy Incubator (CTI) opened December 2018. The new facility, designed and monitored for Good Manufacturing Practice (GMP)-compliance, adds value to the Cleveland Cord Blood Center (CCBC) and helps move innovative cellular therapy products from Research & Development to FDA approval. CTI also serves as a bridge to commercialization of early stage cellular therapy products.

### Driving innovation

“We have the freedom to move forward as a small, independent organization to accommodate innovation. Our ability to manufacture cell therapy products, such as enhanced cord blood products, is an acknowledgement of what we represent as an organization. With critical know-how in all stages of clinical development, and the facility and staff to support customers, CTI leverages the Cleveland Cord Blood Center’s expertise, demonstrated quality, and regulatory and manufacturing expertise to create a much-needed independent laboratory for the cellular therapy industry,” said CCBC Cord Blood Bank Director Wouter Van’t Hof.

Contracting with an independent laboratory, such as CTI for resourcing, process development and the scale up to support clinical development, is a well-established path laid out in the pharmaceutical industry to reach therapeutic proof of concept

for drugs. CCBC aims to apply that same principle to the yet evolving, but rapidly advancing, field of cell therapy and regenerative medicine.

### Ultimate goal: help treat more patients

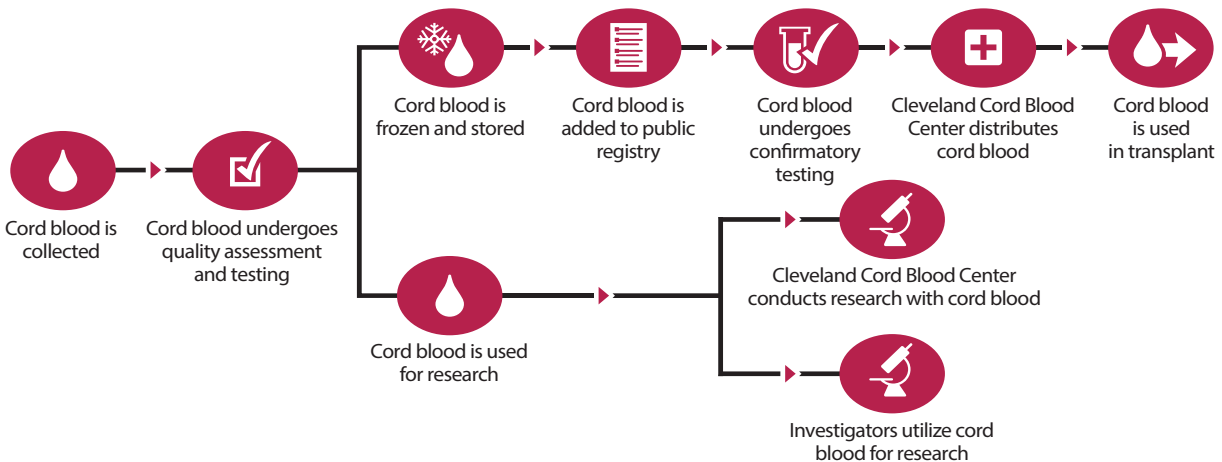
“CTI helps fill a critical gap for academic research teams and small biotechnology companies that typically do not have the resources to justify large capital investments for a facility of this type. We’re looking to add value for our customers by decreasing time to market, overcoming regulatory hurdles and developing quality products,” explained CCBC Executive Director Marcie Finney.

“We see the work we can do for customers ultimately translating into treating more patients by moving cellular therapy products from Research & Development to FDA approval,” Finney noted.



The CCBC CTI will help fill a gap in the manufacture of cell therapy products

## Guide to Cleveland Cord Blood Center banking



# Dual stem cell therapy explored to treat Parkinson's disease

Parkinson's disease (PD) is a debilitating neurodegenerative disease affecting nearly 1 million Americans, with a notably higher estimated prevalence in Midwestern states. PD involves the gradual degeneration of neurons that produce dopamine, which ultimately results in debilitating motor deficits. While the standard treatment regimen can alleviate symptoms, it often loses effectiveness over prolonged treatment. What's more, existing therapies have limited effectiveness in controlling or reversing disease progression long-term.

## New therapeutic approach

Cleveland Cord Blood Center researchers, under lead researcher Daniel Zwick, Ph.D., are exploring an innovative, new therapeutic approach using two types of cord blood stem cells. CCBC researchers hypothesize that a dual stem cell therapy, consisting of mesenchymal stem cells (MSC) and hematopoietic stem cells (HSC), both derived from cord blood, will have complementary effects that benefit Parkinson's disease therapy.

In addition, the researchers plan to explore the administration of stem cells in conjunction with deep brain stimulation (DBS).

## Pre-clinical studies seek optimal ratio

The researchers are currently conducting pre-clinical studies. Preliminary results have shown that stem cells dramatically enhance neuroprotection, with researchers seeking to determine the optimal ratio of MSCs and HSCs for therapeutic effect in these studies. Following proof of concept work, the research team plans to complete clinical manufacturing steps in CCBC's facility to rapidly transition their approach to a Phase I safety clinical trial.

Earlier work by Dr. Mary J. Laughlin, founder and medical director of the Cleveland Cord Blood Center, served as a foundation for the organization's Parkinson's disease research.



Daniel Zwick, Ph.D., leads CCBC Parkinson's disease research



Parents Natalie Wallace and Luther Cuffy were happy to donate baby Nate's cord blood

## Parents recognize value of cord blood donation

When their son Nate was born in October 2017, parents Natalie Wallace and Luther Cuffy of San Francisco didn't hesitate to donate their baby's umbilical cord blood at Kaiser Permanente San Francisco Medical Center, a hospital partner of the Cleveland Cord Blood Center.

Wallace, whose roots are European, and Luther, an African-American, understood the importance of diversifying the blood bank with the Cleveland Cord Blood Center, increasing the potential for a donor match for someone of similar ancestry.

"It's exciting to think of the benefits that cord blood offers. We are happy we can provide it if we can help someone who is going through blood cancer," said Wallace, a registered nurse.

She found cord blood donation to be incredibly easy, "with no interruption at Nate's birth, or during my bonding time with him," she noted. "As an RN, I wish it would become the normal thing for everyone to do. It did not feel invasive at all."

"Cord blood is precious...it's like gold, and has so much potential to help so many," she added.