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## eHCTERS - Registration Information

### Submitted Registration Information

This information has been submitted to the FDA  
Please Remember Your Confirmation Number to Reference this registration submission  
**YOUR CONFIRMATION NUMBER IS: 54467**

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FEI: 3000719146

#### Other FDA Registrations

- ☐ Blood  
☐ Devices  
☐ Drug

#### Reason for Submission

- ☐ Initial Registration/Listing  
☒ Annual Registration/Listing  
☐ Change in Information  
☐ In-Activate Registration

#### Physical Location

Legal Name: ClinImmune Labs-Univ Colorado Cord Blood Bank and Stem Cell Laboratory  
Street Address: 12705 E. Montview Boulevard  
Suite 250  
City: Aurora  
State: Colorado  
Postal Code: 80045  
Country: UNITED STATES  
Phone: 303-724-0535 ext.

#### Reporting Official Information

First Name: Brian M.  
Last Name: Freed Ph.D.  
Title: Executive Director  
Phone: 303-724-0535 Ext.  
E-Mail Address: brian.freed@cuanschutz.edu

#### Mailing Address of Reporting Official

Institution Name: ClinImmune Labs-Univ Colorado Cord Blood Bank and Stem Cell Laboratory  
Street Address: 12705 E. Montview Boulevard  
Suite 250  
City: Aurora  
State: Colorado  
Postal Code: 80045  
Country: UNITED STATES

### HCT/P Listing Information

Types of HCT/Ps	HCT/Ps Described in 21 CFR 1271.10	Date of Discontinuance (mm/dd/yyyy)	Date of Resumption (mm/dd/yyyy)	Proprietary Names
Amniotic Membrane	D	11/16/2021		
Blood Vessel				
Bone				

Cardiac Tissue - non-valved				
Cartilage				
Cornea				
Dura Mater				
Embryo				
Fascia				
Heart Valve				
HPC Apheresis	X			
HPC Cord Blood	X			
Ligament				
Nerve Tissue				
Oocyte				
Ovarian Tissue				
Pancreatic Islet Cells - autologous				
Parathyroid	X			
Pericardium				
Peripheral Blood Mononuclear Cells				
Peritoneal Membrane				
Sclera				
Semen				
Skin				
Tendon				
Testicular Tissue				
Tooth Pulp				
Umbilical Cord Tissue	X			

## HCT/P Listing - Function Information

Types of HCT/Ps	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute
Amniotic Membrane								
Blood Vessel								
Bone								
Cardiac Tissue - non-valved								
Cartilage								
Cornea								
Dura Mater								
Embryo								
Fascia								
Heart Valve								
HPC Apheresis				<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
HPC Cord Blood	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Ligament								
Nerve Tissue								
Oocyte								
Ovarian Tissue								
Pancreatic Islet Cells - autologous								
Parathyroid				<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Pericardium								
Peripheral Blood Mononuclear Cells								
Peritoneal Membrane								
Sclera								
Semen								
Skin								
Tendon								
Testicular Tissue								
Tooth Pulp								
Umbilical Cord Tissue	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

## HCT/P Listing - Donor Information

Types of HCT/Ps	SIP	Directed	Anonymous	Autologous	Family Related
Embryo					
HPC Apheresis				<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
HPC Cord Blood				<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Oocyte					
Peripheral Blood Mononuclear Cells					
Semen					

## Additional Information

Removal of amniotic membrane- none were collected due to anticipated contract for collection cancelled.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION  
ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,  
TISSUES AND CELLULAR AND TISSUE-BASED PRODUCTS (eHCTERS)

eHCTERS v02.13.01  
Updated 11/20/2020

FDA information collection OMB Control number: 0910-0543  
Expiration Date: 07/31/2023

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