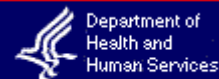




# U.S. Food and Drug Administration



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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 FORM FDA - 3356 Submission  
**YOUR CONFIRMATION NUMBER IS: 40961**

Please print this document and maintain as confirmation of your submission.  
This application is no longer accessible using your pre-confirmation number.

FEI: 3004125624

#### Other FDA Registrations

- Blood FDA 2830  
 Devices FDA 2891  
 Drug FDA 2656

#### Reason for Submission

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

#### Physical Location

Legal Name: DCI Donor Services dba Tennessee Donor Services (Nashville)  
Street Address: 1600 Hayes Street, Suite 300  
City: Nashville  
State: Tennessee  
Postal Code: 37203  
Country: United States  
Phone: 615-564-3600 ext.

#### Reporting Official Information

First Name: Jaree F.  
Last Name: Knopp  
Title: Manager of Quality and Compliance  
Phone: 615-564-3660 Ext.  
E-Mail Address: jknopp@dcids.org

#### Mailing Address of Reporting Official

Institution Name: Tennessee Donor Services  
Street Address: 1600 Hayes Street  
Suite 300  
City: Nashville  
State: Tennessee  
Postal Code: 37203  
Country: United States

#### HCT/P Listing Information

	Types of HCT/P's	HCT/P's Described in 21 CFR 1271.10	HCT/P's Regulated as Medical Devices	HCT/P's Regulated as Drugs or Biological Drugs	Proprietary Names
a.	Bone	X			
b.	Cartilage	X			
c.	Cornea	X			

d.	Dura Mater				
e.	Embryo				
f.	Fascia	X			
g.	Heart Valve	X			
h.	Ligament	X			
i.	Oocyte				
j.	Pericardium	X			
k.	Peripheral Blood Stem Cells				
l.	Sclera	X			
m.	Semen				
n.	Skin	X			
o.	Somatic Cell Therapy Products				
p.	Tendon	X			
q.	Umbilical Cord Blood Stem Cells				
r.	Vascular Graft	X			
s.	Nerve Tissue	X			

### HCT/P Listing - Function Information

	Types of HCT/P's	Recover	Screen	Test	Package	Process	Store	Label	Distribute
a.	Bone		<input checked="" type="checkbox"/>						
b.	Cartilage		<input checked="" type="checkbox"/>						
c.	Cornea		<input checked="" type="checkbox"/>						
d.	Dura Mater								
e.	Embryo								
f.	Fascia		<input checked="" type="checkbox"/>						
g.	Heart Valve		<input checked="" type="checkbox"/>						
h.	Ligament		<input checked="" type="checkbox"/>						
i.	Oocyte								
j.	Pericardium		<input checked="" type="checkbox"/>						
k.	Peripheral Blood Stem Cells								
l.	Sclera		<input checked="" type="checkbox"/>						
m.	Semen								
n.	Skin		<input checked="" type="checkbox"/>						
o.	Somatic Cell Therapy Products								
p.	Tendon		<input checked="" type="checkbox"/>						
q.	Umbilical Cord Blood Stem Cells								
r.	Vascular Graft		<input checked="" type="checkbox"/>						
s.	Nerve Tissue		<input checked="" type="checkbox"/>						

### HCT/P Listing - Donor Information

	Types of HCT/P's	SIP	Directed	Anonymous	Autologous	Family Related	Allogeneic
e.	Embryo						
i.	Oocyte						
k.	Peripheral Blood Stem Cells						
m.	Semen						
o.	Somatic Cell Therapy Products						
q.	Umbilical Cord Blood Stem Cells						

Select New Establishment

CBER On-Line Main Menu

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 v02.08.00  
 Updated 06/27/2014

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