

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b> (See reverse side for instructions)	<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 3004125629	<b>2. REASON FOR SUBMISSION</b> a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:30-NOV-2017 DISTRICT: New Orleans PRINTED BY FDA:27-JAN-2018
---	--	--	--

PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION												14. PROPRIETARY NAME(S)	
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps								11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS			
	Types of HCT / Ps		Establishment Functions											
		Recover	Screen	Test	Package	Process	Store	Label	Distribute					
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) DCI Donor Services dba Tennessee Donor Services (Knoxville)  7015 Middlebrook Pike Knoxville, Tennessee 37909  a. PHONE 865-588-1031 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		a. Bone		X							X			
		b. Cartilage		X						X				
		c. Cornea		X						X				
		d. Dura Mater												
		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
		f. Fascia		X						X				
		g. Heart Valve		X						X				
		h. Ligament		X						X				
		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
		j. Pericardium		X						X				
		k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
		l. Sclera		X						X				
		m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
5. ENTER CORRECTIONS TO ITEM 4		n. Skin		X						X				
		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Tennessee Donor Services Attn: Monika Liggins, 1600 Hayes St. Suite 300 Nashville, Tennessee 37203  a. PHONE 615-564-3660 EXT _____		p. Tendon		X							X			
		q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
7. ENTER CORRECTIONS TO ITEM 6 a. E-MAIL _____ b. PHONE _____		r. Vascular Graft		X						X				
8. U.S. AGENT		s. Nerve Tissue		X						X				
		t.												
		u.												
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Monika Liggins, b. E-MAIL mliggens@dcids.org c. TITLE Manager of Quality and Compliance d. DATE 30-NOV-2017		v.												