

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)		1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 3009250140	2. REASON FOR SUBMISSION a. <input checked="" type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:29-NOV-2011 DISTRICT: Kansas City PRINTED BY FDA:29-NOV-2011											
PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION						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	14. PROPRIETARY NAME(S)						
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2856 NO. _____		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps													
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Donor Services Center 404 Portland Street Columbia, Missouri 65201 a. PHONE 573-443-1471 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		Establishment Functions													
		Types of HCT / Ps	Recover	Screen	Test	Package	Process			Store	Label	Distribute			
5. ENTER CORRECTIONS TO ITEM 4		a. Bone		X							X				
		b. Cartilage		X								X			
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Missouri Lions Eye Research Foundation Attn: Tina M. Livesay 404 Portland Street Columbia, Missouri 65201 a. PHONE 314-428-4373 EXT 101		c. Cornea		X								X			
		d. Dura Mater													
7. ENTER CORRECTIONS TO ITEM 6		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
		f. Fascia		X								X			
8. U.S. AGENT a. E-MAIL _____		g. Heart Valve		X								X			
		h. Ligament		X									X		
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Tina M. Livesay b. E-MAIL tlivesay@mierf.org c. TITLE Chief Compliance Officer d. DATE 28-OCT-2011		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													
		n. Skin		X									X		
		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
		p. Tendon		X									X		
		q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
		r. Vascular Graft		X									X		
		s.													
		t.													
		u.													
		v.													