

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: 3001236481

2. REASON FOR SUBMISSION
a. INITIAL REGISTRATION / LISTING
b. ANNUAL REGISTRATION / LISTING
c. CHANGE IN INFORMATION
d. INACTIVE

VALIDATION--FOR FDA USE ONLY
VALIDATED BY FDA:14-DEC-2009
DISTRICT: Baltimore
PRINTED BY FDA:18-DEC-2009

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	14. PROPRIETARY NAME(S)
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)		Establishment Functions												
5. ENTER CORRECTIONS TO ITEM 4		Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute				
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		a. Bone												
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Lions Medical Eye Bank & Research Center of Eastern Virginia, Inc. 600 Gresham Dr. Norfolk, Virginia 23507 a. PHONE 757-388-2020 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		b. Cartilage												
5. ENTER CORRECTIONS TO ITEM 4		c. Cornea	X	X		X	X	X	X	X	X			
		d. Dura Mater												
		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
		f. Fascia												
5. ENTER CORRECTIONS TO ITEM 4		g. Heart Valve												
		h. Ligament												
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
Lions Medical Eye Bank & Research Center of Eastern Virginia, Inc. Attn: David E. Korroch, CEBT 600 Gresham Dr. Norfolk, Virginia 23507		j. Pericardium												
		k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
a. PHONE 757-388-2020 EXT _____		l. Sclera	X	X		X	X	X	X	X	X			Split-Thickness Sclera "STS"
7. ENTER CORRECTIONS TO ITEM 6		m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
b. PHONE _____		n. Skin												
		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
8. U.S. AGENT		p. Tendon												
		q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
a. E-MAIL		r. Vascular Graft												
9. REPORTING OFFICIAL'S SIGNATURE		s.												
		t.												
a. TYPED NAME David E. Korroch, CEBT		u.												
b. E-MAIL drroch@lionseyebank.org		v.												
c. TITLE Executive Director														
d. DATE 11-DEC-2009														