

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) <i>(See reverse side for instructions)</i>	1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 3002789645	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input checked="" type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:25-JUN-2009 DISTRICT: Detroit PRINTED BY FDA:25-JUN-2009
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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	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps											
	Types of HCT / Ps	Establishment Functions										
		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	X			X		X	X	X	X		
4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> Indiana Organ Procurement Organization 7220 Engle Rd. Fort Wayne, Indiana 46804 a. PHONE 260-436-6023 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	b. Cartilage	X			X		X	X	X	X		
	c. Cornea	X			X		X	X		X		
	d. Dura Mater						X			X		
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
	f. Fascia	X			X		X	X		X		
	g. Heart Valve	X			X		X	X		X		
	h. Ligament	X			X		X	X		X		
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
	j. Pericardium	X			X		X	X		X		
	k. Peripheral Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
l. Sclera												
m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
5. ENTER CORRECTIONS TO ITEM 4	n. Skin	X			X		X	X		X		
6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> Indiana Organ Procurement Organization Attn: Kristi J. Winegarden, PHR 3760 Guion Road Indianapolis, Indiana 46222 a. PHONE 317-685-0389 EXT _____	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
7. ENTER CORRECTIONS TO ITEM 6	p. Tendon	X			X		X	X	X	X		
8. U.S. AGENT a. E-MAIL _____	q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Kristi J. Winegarden, PHR b. E-MAIL kristiw@iopo.org c. TITLE Director, Quality and Regulatory Affairs d. DATE 09-JUN-2009	r. Vascular Graft	X			X		X	X		X		
	s.											
	t.											
	u.											
	v.											