


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: 3007203807	2. REASON FOR SUBMISSION 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	VALIDATION--FOR FDA USE ONLY 1 VALIDATED BY FDA:07-DEC-2009 DISTRICT: Dallas PRINTED BY FDA:18-DEC-2009
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION										14. 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 2656 NO. _____	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2" style="width:25%;">Types of HCT / Ps</th> <th colspan="8" style="text-align: center;">Establishment Functions</th> <th rowspan="2">Recover</th> <th rowspan="2">Screen</th> <th rowspan="2">Test</th> <th rowspan="2">Package</th> <th rowspan="2">Process</th> <th rowspan="2">Store</th> <th rowspan="2">Label</th> <th rowspan="2">Distribute</th> </tr> <tr> <th>Recover</th> <th>Screen</th> <th>Test</th> <th>Package</th> <th>Process</th> <th>Store</th> <th>Label</th> <th>Distribute</th> </tr> </thead> </table>										Types of HCT / Ps	Establishment Functions								Recover	Screen	Test	Package	Process	Store	Label	Distribute	Recover	Screen	Test	Package	Process	Store	Label	Distribute			
Types of HCT / Ps	Establishment Functions								Recover	Screen		Test	Package	Process	Store	Label	Distribute																					
	Recover	Screen	Test	Package	Process	Store	Label	Distribute																														
4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> RTI Donor Services - Corpus Christi 101 North Shoreline Boulevard, Suite 207 Corpus Christi, Texas 78401 a. PHONE 361-904-0510 EXT _____ b. <input checked="" type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3006042944) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone	X	X														X																					
	b. Cartilage	X	X															X																				
	c. Cornea	X	X															X																				
	d. Dura Mater																																					
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																																					
	f. Fascia	X	X															X																				
	g. Heart Valve	X	X															X																				
	h. Ligament	X	X															X																				
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																																					
	j. Pericardium	X	X															X																				
5. ENTER CORRECTIONS TO ITEM 4 6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> RTI Donor Services Attn: Beverly Bliss 11621 Research Circle Alachua, Florida 32615 a. PHONE 386-418-8888 EXT _____	k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																																					
	l. Sclera	X	X															X																				
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																																					
	n. Skin	X	X															X																				
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																																					
	p. Tendon	X	X															X																				
	q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																																					
	r. Vascular Graft	X	X															X																				
	s. Nerve Tissue	X	X															X																				
	t. _____																																					
u. _____																																						
v. _____																																						
7. ENTER CORRECTIONS TO ITEM 6 a. PHONE _____ EXT _____ b. PHONE _____																																						
8. U.S. AGENT a. E-MAIL _____																																						
9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Beverly Bliss b. E-MAIL bbliss@rtix.com c. TITLE Vice President, RTI Donor Services d. DATE 04-DEC-2009																																						