

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 (FDA Establishment Identifier) FEI: 3003934255	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 VALIDATED BY FDA:16-DEC-2014 DISTRICT: New England PRINTED BY FDA:22-DEC-2014
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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						
	Establishment Functions																		
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)		Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute									
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Dana - Farber Cancer Institute Connell & O'Reilly Families' Cell Manipulation Core Facility 450 Brookline Ave Boston, Massachusetts 02215 a. PHONE 617-632-3381 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		a. Bone																	
		b. Cartilage																	
		c. Cornea																	
		d. Dura Mater																	
		e. Embryo	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																
		f. Fascia																	
		g. Heart Valve																	
		h. Ligament																	
		i. Oocyte	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																
		j. Pericardium																	
		k. Peripheral Blood Stem	<input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic				X	X	X	X	X	X	X	X	X	X	X	X	X
		l. Sclera																	
		m. Semen	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																
		5. ENTER CORRECTIONS TO ITEM 4		n. Skin															
				o. Somatic Cell Therapy Products	<input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic				X	X	X	X	X			X	X		
p. Tendon																			
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Dana Farber Cancer Institute Attn: Jerome Ritz, MD Connell & O'Reilly Families' Cell Manipulation Core Facility 450 Brookline Ave Boston, Massachusetts 02215 a. PHONE 617-632-3465 EXT _____ b. PHONE _____		q. Umbilical Cord Blood	<input type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic				X	X	X	X	X	X			X				
		r. Vascular Graft																	
		s. Therapeutic Cells				X	X	X	X	X	X	X			X				
7. ENTER CORRECTIONS TO ITEM 6		t.																	
		u.																	
		v.																	
		8. U.S. AGENT a. E-MAIL _____		t.															
u.																			
v.																			
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Jerome Ritz, MD b. E-MAIL jerome_ritz@dfci.harvard.edu c. TITLE Director d. DATE 15-DEC-2014				t.															
		u.																	
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