

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	11. HCT/PS DESCRIBED IN 21 OFK 12/1/10	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:30%;">Types of HCT / Ps</th> <th colspan="9" style="text-align: center;">Establishment Functions</th> </tr> <tr> <th style="width:5%;">Recover</th> <th style="width:5%;">Screen</th> <th style="width:5%;">Test</th> <th style="width:5%;">Package</th> <th style="width:5%;">Process</th> <th style="width:5%;">Store</th> <th style="width:5%;">Label</th> <th style="width:5%;">Distribute</th> <th style="width:5%;"></th> </tr> </thead> </table>					Types of HCT / Ps	Establishment Functions									Recover	Screen	Test	Package	Process	Store	Label	Distribute	
Types of HCT / Ps	Establishment Functions																							
	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 l. Sclera m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous n. Skin o. Somatic Cell Therapy Products <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic p. Tendon q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic r. Vascular Graft																							
5. ENTER CORRECTIONS TO ITEM 4																								
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 _____	s. Therapeutic Cells t. u. v.																							
7. ENTER CORRECTIONS TO ITEM 6																								
8. U.S. AGENT a. E-MAIL _____																								
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																								