

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: 0001270007

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

VALIDATION-FOR FDA USE ONLY
 DISTRICT: New England
 PRINTED BY FDA-20-JUL-2010

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				
3. OTHER FDA REGISTRATIONS		Types of HCT / Ps		Establishment Functions					12. HCT/PS REGULATED AS MEDICAL DEVICES				
3. OTHER FDA REGISTRATIONS		Types of HCT / Ps		Recover	Screen	Test	Package	Process	Store	Label	Distribute	13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS	
3. OTHER FDA REGISTRATIONS		Types of HCT / Ps		Recover	Screen	Test	Package	Process	Store	Label	Distribute	13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS	
a. BLOOD FDA 2830 NO. FEI: 0001270007		a. Bone											
b. DEVICES FDA 2891 NO.		b. Cartilage											
c. DRUG FDA 2656 NO.		c. Cornea											
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)		d. Dura Mater											
Rhode Island Blood Center 405 Promenade Street Providence, Rhode Island 02908		e. Embryo	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
a. PHONE 401-453-8599 EXT		f. Fascia											
b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____)		g. Heart Valve											
c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		h. Ligament											
5. ENTER CORRECTIONS TO ITEM 4		i. Oocyte	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)		j. Pericardium											
Rhode Island Blood Center Attn: Lawrence F. Smith 405 Promenade Street Providence, Rhode Island 02908		k. Peripheral Blood Stem Cells	<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
a. PHONE 401-453-8599 EXT		l. Sclera											
7. ENTER CORRECTIONS TO ITEM 6		m. Semen	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
b. PHONE		n. Skin											
8. U.S. AGENT		o. Somatic Cell Therapy Products	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
a. E-MAIL		p. Tendon											
9. REPORTING OFFICIAL'S SIGNATURE		q. Umbilical Cord Blood Stem Cells	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic	X	X	X	X	X	X	X	X	X	X
Lawrence F. Smith		r. Vascular Graft											
a. TYPED NAME Lawrence F. Smith		s. Therapeutic Cells		X	X	X	X	X	X	X	X	X	X
b. E-MAIL lsmith@rbc.org		t.											
c. TITLE President and Chief Executive Officer		u.											
d. DATE 15-JUL-2010		v.											