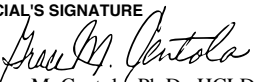


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)	1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3002733251	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:17-NOV-2017 DISTRICT: New England PRINTED BY FDA:27-JAN-2018
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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 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="8" style="text-align: center;">Establishment Functions</th> <th rowspan="2">11. HCT/Ps DESCRIBED IN 21 CFR 1271.10</th> <th rowspan="2">12. HCT/Ps REGULATED AS MEDICAL DEVICES</th> <th rowspan="2">13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS</th> <th rowspan="2">14. PROPRIETARY NAME(S)</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								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)	Recover	Screen	Test	Package	Process	Store	Label	Distribute																																																																																																																																																																																																																																																																																																																
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4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) New England Cryogenic Center, Inc. 500 Donald J. Lynch Blvd Marlborough, Massachusetts 01752 a. PHONE 508-305-2548 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	<table border="1" style="width:100%; border-collapse: collapse;"> <tr><td>a. Bone</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>b. Cartilage</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>c. Cornea</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>d. Dura Mater</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>e. Embryo</td><td></td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td>X</td><td>X</td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>f. Fascia</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>g. Heart Valve</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>h. Ligament</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>i. Oocyte</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>X</td><td>X</td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>j. Pericardium</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>k. Peripheral Blood Stem</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>l. Sclera</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>m. Semen</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>X</td><td>X</td><td></td><td></td></tr> <tr><td>n. Skin</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>o. Somatic Cell Therapy Products</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>p. Tendon</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>q. Umbilical Cord Blood</td><td></td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td>X</td><td>X</td><td></td><td></td></tr> <tr><td>r. Vascular Graft</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>s. Ovarian Tissue</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>X</td><td>X</td><td></td><td></td></tr> <tr><td>t. Testicular Tissue</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>X</td><td>X</td><td></td><td></td></tr> <tr><td>u. Tooth Pulp</td><td></td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td>X</td><td>X</td><td></td><td></td></tr> <tr><td>v. Umbilical Cord</td><td></td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td><td>X</td><td>X</td><td></td><td></td></tr> </table>					a. Bone													b. Cartilage													c. Cornea													d. Dura Mater													e. Embryo							X		X	X																f. Fascia													g. Heart Valve													h. Ligament													i. Oocyte									X	X																j. Pericardium													k. Peripheral Blood Stem																										l. Sclera													m. Semen									X	X			n. Skin													o. Somatic Cell Therapy Products													p. Tendon													q. Umbilical Cord Blood							X		X	X			r. Vascular Graft													s. Ovarian Tissue									X	X			t. Testicular Tissue									X	X			u. Tooth Pulp							X		X	X			v. Umbilical Cord							X		X	X		
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9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Grace M. Centola, Ph.D., HCLD (ABB) b. E-MAIL gcentola@necryogenic.com c. TITLE Tissue Bank Director	d. DATE 16-NOV-2017																																																																																																																																																																																																																																																																																																																																									