

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,          AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS)</b> <small>(See reverse side for instructions)</small>		<b>1. REGISTRATION NUMBER</b> <small>(FDA Establishment Identifier)</small>  FEI: 3005374514	<b>2. REASON FOR SUBMISSION</b> 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	<b>VALIDATION--FOR FDA USE ONLY</b> <small>1</small> VALIDATED BY FDA:16-NOV-2016 DISTRICT: New England PRINTED BY FDA:15-DEC-2016	
--	--	---	--	--	--

  

<b>PART I - ESTABLISHMENT INFORMATION</b> <b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____ <b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) New England Cryogenic Center, Inc.  188 Needham Street Suite 230 Newton, Massachusetts 02464  a. PHONE 617-631-8380 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	<b>PART II - PRODUCT INFORMATION</b> <b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <th rowspan="2" style="width:25%;">Types of HCT / Ps</th> <th colspan="8">Establishment Functions</th> <th rowspan="2" style="width:5%;">11. HCT/PS DESCRIBED IN 21 OFK 1271.10</th> <th rowspan="2" style="width:5%;">12. HCT/PS REGULATED AS MEDICAL DEVICES</th> <th rowspan="2" style="width:5%;">13. HCT/PS REGULATED AS BIOLOGICAL DRUGS</th> <th rowspan="2" style="width:15%;">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> <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></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td><input type="checkbox"/> SIP</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><input type="checkbox"/> Directed</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><input type="checkbox"/> Anonymous</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></td><td></td><td></td><td></td></tr> <tr><td></td><td><input type="checkbox"/> SIP</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><input type="checkbox"/> Directed</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><input checked="" type="checkbox"/> Anonymous</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><input type="checkbox"/> Autologous</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><input type="checkbox"/> Family Related</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><input type="checkbox"/> Allogeneic</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></td><td></td><td></td><td></td></tr> <tr><td></td><td><input checked="" type="checkbox"/> SIP</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><input checked="" type="checkbox"/> Directed</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><input checked="" type="checkbox"/> Anonymous</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>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></td><td><input type="checkbox"/> Autologous</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><input type="checkbox"/> Family Related</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><input type="checkbox"/> Allogeneic</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></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td></td><td><input type="checkbox"/> Autologous</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><input type="checkbox"/> Family Related</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><input type="checkbox"/> Allogeneic</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>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. Testicular Tissue</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>t.</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>u.</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>v.</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> </table>	Types of HCT / Ps	Establishment Functions								11. HCT/PS DESCRIBED IN 21 OFK 1271.10	12. HCT/PS REGULATED AS MEDICAL DEVICES	13. HCT/PS REGULATED AS BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)	Recover	Screen	Test	Package	Process	Store	Label	Distribute	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 checked="" type="checkbox"/> Anonymous												j. Pericardium													k. Peripheral Blood Stem														<input type="checkbox"/> Autologous													<input type="checkbox"/> Family Related													<input type="checkbox"/> Allogeneic												l. Sclera													m. Semen														<input checked="" type="checkbox"/> SIP													<input checked="" type="checkbox"/> Directed													<input checked="" type="checkbox"/> Anonymous												n. Skin													o. Somatic Cell Therapy Products														<input type="checkbox"/> Autologous													<input type="checkbox"/> Family Related													<input type="checkbox"/> Allogeneic												p. Tendon													q. Umbilical Cord Blood														<input type="checkbox"/> Autologous													<input type="checkbox"/> Family Related													<input type="checkbox"/> Allogeneic												r. Vascular Graft													s. Testicular Tissue																										t.													u.													v.												
Types of HCT / Ps	Establishment Functions								11. HCT/PS DESCRIBED IN 21 OFK 1271.10	12. HCT/PS REGULATED AS MEDICAL DEVICES					13. HCT/PS REGULATED AS BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
	Recover	Screen	Test	Package	Process	Store	Label	Distribute																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																			
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 checked="" type="checkbox"/> Anonymous																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																										
j. Pericardium																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
k. Peripheral Blood Stem																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
	<input type="checkbox"/> Autologous																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																										
	<input type="checkbox"/> Family Related																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																										
	<input type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																										
l. Sclera																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
m. Semen																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
	<input checked="" type="checkbox"/> SIP																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																										
	<input checked="" type="checkbox"/> Directed																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																										
	<input checked="" type="checkbox"/> Anonymous																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																										
n. Skin																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
o. Somatic Cell Therapy Products																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
	<input type="checkbox"/> Autologous																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																										
	<input type="checkbox"/> Family Related																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																										
	<input type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																										
p. Tendon																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
q. Umbilical Cord Blood																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
	<input type="checkbox"/> Autologous																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																										
	<input type="checkbox"/> Family Related																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																										
	<input type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																										
r. Vascular Graft																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
s. Testicular Tissue																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
t.																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
u.																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											
v.																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																											

  

<b>5. ENTER CORRECTIONS TO ITEM 4</b>  <b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) New England Cryogenic Center Attn: Grace M. Centola, Ph.D., HCLD 188 Needham Street Suite 230 Newton, Massachusetts 02464  a. PHONE 617-631-8380 EXT _____	<b>7. ENTER CORRECTIONS TO ITEM 6</b> b. PHONE _____  <b>8. U.S. AGENT</b>  a. E-MAIL _____  <b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Grace M. Centola, Ph.D., HCLD b. E-MAIL gcentola@necryogenic.com c. TITLE Tissue Bank Director d. DATE 15-NOV-2016
--	---

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE

**1. REGISTRATION NUMBER**  
(FDA Establishment Identifier)

2

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)

FEI: 3005374514

**ADDITIONAL INFORMATION:**

Testicular tissue from SIP (client depositors) only

**Proprietary Name(s):**