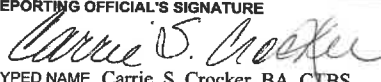


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS)</b> (See reverse side for instructions)	<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 1000307504	<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> 1 VALIDATED BY FDA:03-DEC-2016 DISTRICT: New Orleans 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) DCI Donor Services Tissue Bank  1714 Hayes Street Nashville, Tennessee 37203  a. PHONE 615-234-5200 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;"> <thead> <tr> <th rowspan="2" style="width:30%;">Types of HCT / Ps</th> <th colspan="8">Establishment Functions</th> <th rowspan="2" style="width:5%;">11. HCT/PS DESCRIBED IN 21 CFR 127.110</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 DRUGS OR 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> </thead> <tbody> <tr><td>a. Bone</td><td></td><td>X</td><td></td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td></td><td></td><td></td></tr> <tr><td>b. Cartilage</td><td></td><td>X</td><td></td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</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>f. Fascia</td><td></td><td>X</td><td></td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</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>X</td><td></td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</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>j. Pericardium</td><td></td><td>X</td><td></td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</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>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>n. Skin</td><td></td><td>X</td><td></td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</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>X</td><td></td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</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>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. Amniotic Membrane</td><td></td><td>X</td><td></td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</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> </tbody> </table>			Types of HCT / Ps	Establishment Functions								11. HCT/PS DESCRIBED IN 21 CFR 127.110	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	a. Bone		X		X	X	X	X	X	X				b. 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<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) DCI Donor Services Attn: Carrie S. Crocker, BA, CTBS 1714 Hayes Street Nashville, Tennessee 37203  a. PHONE 615-564-3774 EXT _____ b. PHONE _____	b. <input type="checkbox"/> Autologous c. <input type="checkbox"/> Family Related d. <input type="checkbox"/> Allogeneic  b. <input type="checkbox"/> Directed c. <input type="checkbox"/> Anonymous  b. <input type="checkbox"/> Autologous c. <input type="checkbox"/> Family Related d. <input type="checkbox"/> Allogeneic  b. <input type="checkbox"/> Directed c. <input type="checkbox"/> Anonymous			<b>7. ENTER CORRECTIONS TO ITEM 6</b>  <b>8. U.S. AGENT</b>  a. E-MAIL _____																																																																																																																																																																																																																																																																																																																		
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Carrie S. Crocker, BA, CTBS b. E-MAIL ccrocker@dcds.org c. TITLE Sr. Director, GTP Quality Systems d. DATE 02-DEC-2016																																																																																																																																																																																																																																																																																																																						