


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: 3001779663	<b>2. REASON FOR SUBMISSION</b> a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input checked="" type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:24-APR-2018 DISTRICT: Dallas PRINTED BY FDA:25-JUL-2018																																																																																																																																																																																																																																																																																													
<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>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">Types of HCT / Ps</th> <th colspan="8">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> <tbody> <tr> <td>a. Bone</td> <td>X</td> <td>X</td> <td></td> <td>X</td> <td></td> <td></td> <td></td> <td>X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>b. Cartilage</td> <td>X</td> <td>X</td> <td></td> <td>X</td> <td></td> <td></td> <td></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> </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> </tr> <tr> <td>e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <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>X</td> <td>X</td> <td></td> <td>X</td> <td></td> <td></td> <td></td> <td>X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>g. Heart Valve</td> <td>X</td> <td>X</td> <td></td> <td>X</td> <td></td> <td></td> <td></td> <td>X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>h. Ligament</td> <td>X</td> <td>X</td> <td></td> <td>X</td> <td></td> <td></td> <td></td> <td>X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <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>j. Pericardium</td> <td>X</td> <td>X</td> <td></td> <td>X</td> <td></td> <td></td> <td></td> <td>X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <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> </tr> <tr> <td>m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <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>n. Skin</td> <td>X</td> <td>X</td> <td></td> <td>X</td> <td></td> <td></td> <td></td> <td>X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <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>X</td> <td>X</td> <td></td> <td>X</td> <td></td> <td></td> <td></td> <td>X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <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>X</td> <td>X</td> <td></td> <td>X</td> <td></td> <td></td> <td></td> <td>X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>s. Amniotic Membrane</td> <td>X</td> <td>X</td> <td></td> <td>X</td> <td></td> <td></td> <td></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> </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> </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> </tr> </tbody> </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	a. Bone	X	X		X				X				b. Cartilage	X	X		X				X				c. Cornea												d. Dura Mater												e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												f. Fascia	X	X		X				X				g. Heart Valve	X	X		X				X				h. Ligament	X	X		X				X				i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												j. Pericardium	X	X		X				X				k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												l. Sclera												m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												n. Skin	X	X		X				X				o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												p. Tendon	X	X		X				X				q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												r. Vascular Graft	X	X		X				X				s. Amniotic Membrane	X	X		X				X				t.												u.												v.											
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																																																																																																																																																																																																																																																																																								
a. Bone	X	X		X				X																																																																																																																																																																																																																																																																																								
b. Cartilage	X	X		X				X																																																																																																																																																																																																																																																																																								
c. Cornea																																																																																																																																																																																																																																																																																																
d. Dura Mater																																																																																																																																																																																																																																																																																																
e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																																																																																																																																																																																																																																																																																																
f. Fascia	X	X		X				X																																																																																																																																																																																																																																																																																								
g. Heart Valve	X	X		X				X																																																																																																																																																																																																																																																																																								
h. Ligament	X	X		X				X																																																																																																																																																																																																																																																																																								
i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																																																																																																																																																																																																																																																																																																
j. Pericardium	X	X		X				X																																																																																																																																																																																																																																																																																								
k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																																																																
l. Sclera																																																																																																																																																																																																																																																																																																
m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																																																																																																																																																																																																																																																																																																
n. Skin	X	X		X				X																																																																																																																																																																																																																																																																																								
o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																																																																
p. Tendon	X	X		X				X																																																																																																																																																																																																																																																																																								
q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																																																																
r. Vascular Graft	X	X		X				X																																																																																																																																																																																																																																																																																								
s. Amniotic Membrane	X	X		X				X																																																																																																																																																																																																																																																																																								
t.																																																																																																																																																																																																																																																																																																
u.																																																																																																																																																																																																																																																																																																
v.																																																																																																																																																																																																																																																																																																
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Arkansas Regional Organ Recovery Agency  1701 Aldersgate Road, Suite 4 Little Rock, Arkansas 72205  a. PHONE 501-907-9131 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	<b>5. ENTER CORRECTIONS TO ITEM 4</b>			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																																																																																																																																																																																																																																																																																												
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Arkansas Regional Organ Recovery Agency Attn: Patricia A. Gottschall 1701 Aldersgate Road, Suite 4 Little Rock, Arkansas 72205  a. PHONE 501-749-5731 EXT _____	<b>7. ENTER CORRECTIONS TO ITEM 6</b>			14. PROPRIETARY NAME(S)																																																																																																																																																																																																																																																																																												
<b>8. U.S. AGENT</b>  a. E-MAIL	<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Patricia A. Gottschall b. E-MAIL pgottschall@arora.org c. TITLE Director of Quality Systems d. DATE 23-APR-2018			14. PROPRIETARY NAME(S)																																																																																																																																																																																																																																																																																												