

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: 0001573115	<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> VALIDATED BY FDA:01-FEB-2018 DISTRICT: Cincinnati PRINTED BY FDA:15-FEB-2018
---	--	--	---

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)																																																																																																																																																																																																																																																																																																																																																																																									
<b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. <u>FEI: 0001573115</u> b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	<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" 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																																																																																																																																																																																																																																																																																																																																																																				
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																																																																																																																																																																																																																																																																																																																																																																																						
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) The Ohio State University Medical Center Laboratories  S311 Rhodes Hall 450 W. 10th Avenue Columbus, Ohio 43210  a. PHONE 614-366-4860 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input checked="" 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></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td colspan="13"> <input type="checkbox"/> SIP  <input type="checkbox"/> Directed  <input type="checkbox"/> Anonymous                 </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 colspan="13"> <input type="checkbox"/> SIP  <input type="checkbox"/> Directed  <input type="checkbox"/> Anonymous                 </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 colspan="13"> <input checked="" type="checkbox"/> Autologous  <input checked="" type="checkbox"/> Family Related  <input checked="" type="checkbox"/> Allogeneic                 </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 colspan="13"> <input type="checkbox"/> SIP  <input type="checkbox"/> Directed  <input type="checkbox"/> Anonymous                 </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 colspan="13"> <input checked="" type="checkbox"/> Autologous  <input checked="" type="checkbox"/> Family Related  <input checked="" type="checkbox"/> Allogeneic                 </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 colspan="13"> <input checked="" type="checkbox"/> Autologous  <input checked="" type="checkbox"/> Family Related  <input checked="" type="checkbox"/> Allogeneic                 </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. Pancreatic Islet Cells - autologous</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 colspan="13"> <input checked="" type="checkbox"/> Autologous  <input checked="" type="checkbox"/> Family Related  <input checked="" type="checkbox"/> Allogeneic                 </td></tr> <tr><td>t. Therapeutic Cells</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>					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 type="checkbox"/> Anonymous													j. Pericardium													k. Peripheral Blood Stem													<input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic													l. Sclera													m. Semen													<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													n. Skin													o. Somatic Cell Therapy Products													<input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic													p. Tendon													q. Umbilical Cord Blood													<input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic													r. Vascular Graft													s. Pancreatic Islet Cells - autologous													<input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic													t. Therapeutic Cells													u.													v.												
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 type="checkbox"/> Anonymous																																																																																																																																																																																																																																																																																																																																																																																														
j. Pericardium																																																																																																																																																																																																																																																																																																																																																																																														
k. Peripheral Blood Stem																																																																																																																																																																																																																																																																																																																																																																																														
<input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																																																																																																																																																														
l. Sclera																																																																																																																																																																																																																																																																																																																																																																																														
m. Semen																																																																																																																																																																																																																																																																																																																																																																																														
<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																																																																																																																																																																																																																																																																																																																																																																																														
n. Skin																																																																																																																																																																																																																																																																																																																																																																																														
o. Somatic Cell Therapy Products																																																																																																																																																																																																																																																																																																																																																																																														
<input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																																																																																																																																																														
p. Tendon																																																																																																																																																																																																																																																																																																																																																																																														
q. Umbilical Cord Blood																																																																																																																																																																																																																																																																																																																																																																																														
<input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																																																																																																																																																														
r. Vascular Graft																																																																																																																																																																																																																																																																																																																																																																																														
s. Pancreatic Islet Cells - autologous																																																																																																																																																																																																																																																																																																																																																																																														
<input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic																																																																																																																																																																																																																																																																																																																																																																																														
t. Therapeutic Cells																																																																																																																																																																																																																																																																																																																																																																																														
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) The Ohio State University Medical Center Laboratories Attn: JoAnna D. Williams, MD E310 Doan HALL 410 W. 10th Ave. Columbus, Ohio 43210  a. PHONE 614-366-4860 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 JoAnna D. Williams, MD b. E-MAIL JoAnna.Williams@osumc.edu c. TITLE Laboratory Medical Director	d. DATE 31-JAN-2018																																																																																																																																																																																																																																																																																																																																																																																													