

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 (HCTIPs)**  
(See reverse side for instructions)

1. REGISTRATION NUMBER  
(FDA Establishment Identifier)  
FEI: 3001238005

2. REASON FOR SUBMISSION  
a.  INITIAL REGISTRATION / LISTING  
b.  ANNUAL REGISTRATION / LISTING  
c.  CHANGE IN INFORMATION  
d.  INACTIVE

VALIDATION—FOR FDA USE ONLY  
DISTRICT: Dallas  
PRINTED BY FDA:15-DEC-2016

14. PROPRIETARY NAME(S)

13. HCTIPs REGULATED AS DRUGS OR BIOLOGICAL DRUGS

12. HCTIPs REGULATED AS MEDICAL DEVICES

11. HCTIPs DESCRIBED IN 21 CFR 1271.10

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions						
	Recover	Screen	Test	Package	Process	Store	Distribute
a. Bone	X	X				X	X
b. Cartilage	X	X		X	X	X	X
c. Cornea	X	X		X	X	X	X
d. Dura Mater							
e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous							
f. Fascia	X	X		X	X	X	X
g. Heart Valve	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	X	X		X	X	X	X
m. Sperm <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous							
n. Skin	X	X		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
s. Amniotic Membrane				X	X	X	X
t. Nerve Tissue				X	X	X	X
u.							
v.							

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO. \_\_\_\_\_  
b. DEVICES FDA 2891 NO. \_\_\_\_\_  
c. DRUG FDA 2656 NO. \_\_\_\_\_

4. PHYSICAL LOCATION (include legal name, number and street, city, state, country, and post office code)  
Transplant Services Center UT Southwestern Medical Center  
5323 Harry Hines, MC 9074  
Dallas, Texas 75390-9074

a. PHONE 214-648-2609 EXT \_\_\_\_\_  
b.  SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. \_\_\_\_\_)  
c.  TESTING FOR MICRO-ORGANISMS ONLY

5. ENTER CORRECTIONS TO ITEM 4

6. MAILING ADDRESS OF REPORTING OFFICIAL (include institution name if applicable, number and street, city, state, country, and post office code)  
Transplant Services Center, UT Southwestern Medical Center  
Attn: Kiara M. Cotton, MHA, CTBS  
5323 Harry Hines, MC 9074  
Dallas, Texas 75390-9074

a. PHONE 214-645-8402 EXT \_\_\_\_\_  
b. PHONE \_\_\_\_\_

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT

a. E-MAIL  
9. REPORTING OFFICIAL'S SIGNATURE  
Kiara M. Cotton  
a. TYPED NAME Kiara M. Cotton, MHA, CTBS  
b. E-MAIL kiara.cotton@utsouthwestern.edu  
c. TITLE QA Coordinator  
d. DATE 29-NOV-2016