

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 (HCT/PS)**
(See reverse side for instructions)

1. REGISTRATION NUMBER
(FDA Establishment Identifier)
FEI: 0001077605

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

VALIDATION--FOR FDA USE ONLY
VALIDATED BY FDA: 03-JAN-2015
DISTRICT: New Orleans
PRINTED BY FDA: 02-FEB-2015

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions					11. HCT/PS DESCRIBED IN 21 CFR 1271.10	12. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS	13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
	Recover	Screen	Test	Package	Process				
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 type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic			X						X
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 type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	X					X			X
p. Tendon									
q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic									
r. Vascular Graft									
s. Therapeutic Cells			X						X
t.									
u.									
v.									

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2830 NO. FEI: 0001077605
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)
Medic Regional Blood Center
1601 Ailor Avenue
Knoxville, Tennessee 37921

a. PHONE 865-524-3074 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)
MEDIC Regional Blood Center
Attn: Martha S. Cox, MPH, MT
1601 Ailor Avenue
Knoxville, Tennessee 37921

a. PHONE 865-524-3074 EXT 668
b. PHONE _____

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT

a. E-MAIL _____
b. PHONE _____

9. REPORTING OFFICIAL'S SIGNATURE
Martha S. Cox
a. TYPED NAME Martha S. Cox, MPH, MT
b. E-MAIL mcox@medicblood.org
c. TITLE Chief Quality Officer
d. DATE 02-JAN-2015