JAN 3 2005

See Reverse for OMB Statement

FORM APPROVED: OMB No. 0910-0469. Expiration Date: July 31, 2007

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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 (Field Establishment Identifier): FEI: 3001238006

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

VALIDATION--FOR FDA USE ONLY

VALIDATED BY FDA: 19-DEC-2005
PRINTED BY FDA: 19-DEC-2005
DISTRICT OFFICE: Dallas

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)*

Community Blood Center dba Community Tissue Services
328 South Adams Street
Fort Worth, Texas 76104

PHONE 817-332-1898 EXT

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)*

Community Blood Center/Community Tissue Services
349 S. Main Street
Dayton, Ohio 45402-2715

PHONE 937-461-3450 EXT 3288

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT

a. E-MAIL b. PHONE

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Judith E. Woll, MD
b. E-MAIL jwoll@cbccts.org
c. TITLE CEO d. DATE 08-DEC-2005

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS:
- a [X] RECOVER
- b [X] SCREEN
- c [ ] TEST
- d [ ] PACKAGE
- e [ ] PROCESS
- f [X] STORE
- g [X] LABEL
- h [X] DISTRIBUTE

TYPES OF HCT/Ps	11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES, DRUGS, OR BIOLOGICAL DRUGS	13. PROPRIETARY NAME(S)
a. Bone	X		
b. Cartilage	X		
c. Cornea			
d. Dura Mater			
e. Embryo			
f. Fascia	X		
g. Heart Valve	X		
h. Ligament	X		
i. Oocyte			
j. Pericardium	X		
k. Peripheral Blood Stem Cells			
l. Sclera			
m. Semen			
n. Skin	X		
o. Somatic Cells			
p. Tendon	X		
q. Umbilical Cord Blood Stem Cells			
r. Vascular Graft	X		
s.			
t.			
u.			
v.			

FORM FDA 3356 (8/04) PREVIOUS EDITION IS OBSOLETE.

See Reverse for OMB Statement

FORM APPROVED: OMB No. 0910-0469. Expiration Date: July 31, 2007

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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
(Field Establishment Identifier):
FEI: 3001238006

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

VALIDATION--FOR FDA USE ONLY 1

3001238006

VALIDATED BY FDA: 12-JAN-2007
PRINTED BY FDA: 02-FEB-2007
DISTRICT OFFICE: Dallas

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)*

Community Blood Center dba Community Tissue Services
328 South Adams Street
Fort Worth, Texas 76104

PHONE 817-332-1898 EXT

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)*

Community Blood Center dba Community Tissue Services
Attn: Judith E. Woll, MD
349 S. Main Street
Dayton, Ohio 45402-2715

PHONE 937-461-3261 EXT

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT

a. E-MAIL b. PHONE

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Judith E. Woll, MD
b. E-MAIL jwoll@cbccts.org
c. TITLE CEO d. DATE 01-DEC-2006

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS:

a ☒ RECOVER c ☐ TEST e ☐ PROCESS g ☒ LABEL
b ☒ SCREEN d ☐ PACKAGE f ☒ STORE h ☒ DISTRIBUTE

	TYPES OF HCT/Ps	11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES, DRUGS, OR BIOLOGICAL DRUGS	13. PROPRIETARY NAME(S)
a.	Bone	X		
b.	Cartilage	X		
c.	Cornea			
d.	Dura Mater			
e.	Embryo			
f.	Fascia	X		
g.	Heart Valve	X		
h.	Ligament	X		
i.	Oocyte			
j.	Pericardium	X		
k.	Peripheral Blood Stem Cells			
l.	Sclera			
m.	Semen			
n.	Skin	X		
o.	Somatic Cells			
p.	Tendon	X		
q.	Umbilical Cord Blood Stem Cells			
r.	Vascular Graft	X		
s.				
t.				
u.				
v.				

FORM FDA 3356 (8/04) PREVIOUS EDITION IS OBSOLETE.

See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 7/31/10

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 (Field Establishment Identifier)
FEI: 3001238006

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

VALIDATION--FOR FDA USE ONLY 1
3001238006
VALIDATED By FDA: 12/10/07 **PRINTED By FDA:** 12/17/07
DISTRICT: Dallas

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)*
Community Blood Center dba Community Tissue Services"
328 South Adams Street
Fort Worth, Texas 76104

a. PHONE 817-332-1898 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)*
Community Blood Center dba Community Tissue Services"
Attn: David M. Smith, MD
349 S. Main Street
Dayton, Ohio 45402-2715

a. PHONE 937-461-3450 EXT 3610

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME David M. Smith, MD
b. E-MAIL dsmith@cbccts.org
c. TITLE CEO/Medical Director d. DATE 05-DEC-2007

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 MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
	Recover	Screen	Test	Package	Process	Store	Label	Distribute				
No HCT / P Specified												
a. Bone	X	X				X	X	X	X			
b. Cartilage	X	X				X	X	X	X			
c. Cornea												
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X				X	X	X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X				X	X	X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X							X			
k. Peripheral Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X				X	X	X	X			
o. Somatic Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X				X	X	X	X			
q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X							X			
s.												
t.												
u.												
v.												

FORM FDA 3356 (9/07) PREVIOUS EDITION IS OBSOLETE.

See Instructions for OMB Statement

FORM APPROVED: OMB No. 0910-0543. Expiration Date: 7/31/10

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
(Field Establishment Identifier)

FEI: 3001238006

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

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:27-MAR-2008
DISTRICT: Dallas
PRINTED BY FDA:27-MAR-2008

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)*

Community Blood Center dba Community Tissue Services"
328 South Adams Street
Fort Worth, Texas 76104

a. PHONE 817-332-1898 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)*

Community Blood Center dba Community Tissue Services
Attn: David M. Smith, MD
349 S. Main Street
Dayton, Ohio 45402-2715

a. PHONE 937-461-3450 EXT 3610

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME David M. Smith, MD

b. E-MAIL dsmith@cbccts.org

c. TITLE CEO/Medical Director d. DATE 20-MAR-2008

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 MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
	Recover	Screen	Test	Package	Process	Store	Label	Distribute				
No HCT / P Specified												
a. Bone	X	X				X	X	X	X			
b. Cartilage	X	X				X	X	X	X			
c. Cornea												
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X				X	X	X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X				X	X	X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X				X	X	X	X			
k. Peripheral Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X				X	X	X	X			
o. Somatic Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X				X	X	X	X			
q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X							X			
s.												
t.												
u.												
v.												

FORM FDA 3356 (9/07) PREVIOUS EDITION IS OBSOLETE.

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
(Field Establishment Identifier)
FEI: 3001238006

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

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:30-DEC-2008
DISTRICT: Dallas
PRINTED BY FDA:05-JAN-2009

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)*
Community Blood Center dba Community Tissue Services
328 South Adams Street
Fort Worth, Texas 76104

a. PHONE 817-332-1898 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)*
Community Blood Center dba Community Tissue Services
Attn: David M. Smith, MD
349 S. Main Street
Dayton, Ohio 45402-2715

a. PHONE 937-461-3450 EXT 3610

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME David M. Smith, MD
b. E-MAIL dsmith@cbccts.org
c. TITLE CEO/Medical Director d. DATE 08-DEC-2008

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 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			
b. Cartilage	X	X				X	X	X	X			
c. Cornea												
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X				X	X	X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X				X	X	X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X				X	X	X	X			
k. Peripheral Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X				X	X	X	X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X				X	X	X	X			
q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X							X			
s. Parathyroid						X		X	X			
t. Peritoneal Membrane	X	X				X	X	X	X			
u.												
v.												

See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 8/31/10

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
(Field Establishment Identifier)
FEI: 3001238006

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

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:01-MAY-2009
DISTRICT: Dallas
PRINTED BY FDA:10-AUG-2009

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)*
Community Blood Center dba Community Tissue Services
328 South Adams Street
Fort Worth, Texas 76104

a. PHONE 817-332-1898 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)*
Community Blood Center dba Community Tissue Services
Attn: David M. Smith, MD
349 S. Main Street
Dayton, Ohio 45402-2715

a. PHONE 937-461-3450 EXT 3610

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME David M. Smith, MD
b. E-MAIL dsmith@cbccts.org
c. TITLE CEO d. DATE 30-APR-2009

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions: Recover	Screen	Test	Package	Process	Store	Label	Distribute	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)
a. Bone	X	X				X	X	X	X			
b. Cartilage	X	X				X	X	X	X			
c. Cornea												
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X				X	X	X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X				X	X	X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X				X	X	X	X			
k. Peripheral Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X				X	X	X	X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X				X	X	X	X			
q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X							X			
s. Nerve Tissue						X		X	X			
t. Parathyroid						X		X	X			
u. Peritoneal Membrane	X	X				X	X	X	X			
v.												

See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 8/31/10

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
(Field Establishment Identifier)
FEI: 3001238006

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

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:05-JAN-2010
DISTRICT: Dallas
PRINTED BY FDA:23-FEB-2010

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)*
Community Blood Center dba Community Tissue Services
328 South Adams Street
Fort Worth, Texas 76104

a. PHONE 817-332-1898 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)*
Community Blood Center dba Community Tissue Services
Attn: David M. Smith, MD
349 S. Main Street
Dayton, Ohio 45402-2715

a. PHONE 937-461-3450 EXT 3610

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME David M. Smith, MD
b. E-MAIL dsmith@cbccts.org
c. TITLE CEO d. DATE 29-DEC-2009

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 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			
b. Cartilage	X	X				X	X	X	X			
c. Cornea												
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X				X	X	X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X				X	X	X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X				X	X	X	X			
k. Peripheral Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X				X	X	X	X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X				X	X	X	X			
q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X							X			
s. Nerve Tissue						X		X	X			
t. Parathyroid						X		X	X			
u. Peritoneal Membrane	X	X				X	X	X	X			
v.												

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 (Field Establishment Identifier)
FEI: 3001238006

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

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:29-DEC-2010
DISTRICT: Dallas
PRINTED BY FDA:05-JAN-2011

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)*
Community Blood Center dba Community Tissue Services
328 South Adams Street
Fort Worth, Texas 76104

a. PHONE 817-332-1898 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)*
Community Blood Center dba Community Tissue Services
Attn: David M. Smith, MD
349 S. Main Street
Dayton, Ohio 45402-2715

a. PHONE 937-461-3450 EXT 3610

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME David M. Smith, MD
b. E-MAIL dsmith@cbccts.org
c. TITLE CEO d. DATE 21-DEC-2010

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 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			
b. Cartilage	X	X				X	X	X	X			
c. Cornea												
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X				X	X	X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X				X	X	X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X				X	X	X	X			
k. Peripheral Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X				X	X	X	X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X				X	X	X	X			
q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X							X			
s. Parathyroid						X		X	X			
t. Peritoneal Membrane	X	X				X	X	X	X			
u.												
v.												

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 (Field Establishment Identifier)
FEI: 3001238006

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

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:08-DEC-2011
DISTRICT: Dallas
PRINTED BY FDA:15-DEC-2011

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)*
Community Blood Center dba Community Tissue Services
328 South Adams Street
Fort Worth, Texas 76104

a. PHONE 817-332-1898 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)*
Community Blood Center dba Community Tissue Services
Attn: David M. Smith, MD
349 S. Main Street
Dayton, Ohio 45402-2715

a. PHONE 937-461-3450 EXT 3610

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME David M. Smith, MD
b. E-MAIL dsmith@cbccts.org
c. TITLE CEO d. DATE 07-DEC-2011

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 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			
b. Cartilage	X	X				X	X	X	X			
c. Cornea												
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X				X	X	X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X				X	X	X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X				X	X	X	X			
k. Peripheral Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X				X	X	X	X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X				X	X	X	X			
q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X							X			
s. Parathyroid						X		X	X			
t. Peritoneal Membrane	X	X				X	X	X	X			
u.												
v.												

See Instructions for OMB Statement

FORM APPROVED: OMB No. 0910-0543. Expiration Date: 1/31/14

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: 3001238006

2. REASON FOR SUBMISSION

a. ☐ INITIAL REGISTRATION / LISTING
b. ☒ ANNUAL REGISTRATION / LISTING
c. ☐ CHANGE IN INFORMATION
d. ☐ INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:21-NOV-2012
DISTRICT: Dallas
PRINTED BY FDA:06-DEC-2012

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)

Community Blood Center dba Community Tissue Services

328 South Adams Street
Fort Worth, Texas 76104

a. PHONE 817-332-1898 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)

Community Blood Center dba Community Tissue Services
Attn: David M. Smith, MD
349 S. Main Street
Dayton, Ohio 45402-2715

a. PHONE 937-461-3450 EXT 3610

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME David M. Smith, MD

b. E-MAIL dsmith@cbccts.org

c. TITLE CEO d. DATE 20-NOV-2012

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions: Recover	Screen	Test	Package	Process	Store	Label	Distribute	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)
a. Bone	X	X			X	X		X	X			
b. Cartilage	X	X			X	X		X	X			
c. Cornea												
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X			X	X		X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X			X	X		X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X			X	X		X	X			
k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X			X	X		X	X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X			X	X		X	X			
q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X							X			
s. Parathyroid						X		X	X			
t. Peritoneal Membrane	X	X			X	X		X	X			
u.												
v.												

See Instructions for OMB Statement

FORM APPROVED: OMB No. 0910-0543. Expiration Date: 1/31/14

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: 3001238006

2. REASON FOR SUBMISSION

a. ☐ INITIAL REGISTRATION / LISTING
b. ☒ ANNUAL REGISTRATION / LISTING
c. ☐ CHANGE IN INFORMATION
d. ☐ INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:19-NOV-2013
DISTRICT: Dallas
PRINTED BY FDA:09-DEC-2013

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)

Community Blood Center dba Community Tissue Services

328 South Adams Street
Fort Worth, Texas 76104

a. PHONE 817-332-1898 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)

Community Blood Center dba Community Tissue Services
Attn: David M. Smith, MD
349 S. Main Street
Dayton, Ohio 45402-2715

a. PHONE 937-461-3450 EXT 3610

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME David M. Smith, MD

b. E-MAIL dsmith@cbccts.org

c. TITLE CEO d. DATE 18-NOV-2013

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions: Recover	Screen	Test	Package	Process	Store	Label	Distribute	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)
a. Bone	X	X				X		X	X			
b. Cartilage	X	X				X		X	X			
c. Cornea												
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X				X		X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X				X		X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X				X		X	X			
k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X				X		X	X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X				X		X	X			
q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X							X			
s. Parathyroid						X		X	X			
t. Peritoneal Membrane	X	X				X		X	X			
u.												
v.												

See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 1/31/14

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: 3001238006

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

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:31-DEC-2013
DISTRICT: Dallas
PRINTED BY FDA:27-JAN-2014

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)
Community Blood Center dba Community Tissue Services

328 South Adams Street
Fort Worth, Texas 76104

a. PHONE 817-332-1898 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)
Community Blood Center dba Community Tissue Services
Attn: David M. Smith, MD
349 S. Main Street
Dayton, Ohio 45402-2715

a. PHONE 937-461-3450 EXT 3610

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME David M. Smith, MD
b. E-MAIL dsmith@cbccts.org
c. TITLE CEO d. DATE 30-DEC-2013

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions: Recover	Screen	Test	Package	Process	Store	Label	Distribute	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)
a. Bone	X	X			X	X		X	X			
b. Cartilage	X	X			X	X		X	X			
c. Cornea												
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X			X	X		X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X			X	X		X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X			X	X		X	X			
k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X			X	X		X	X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X			X	X		X	X			
q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X							X			
s. Parathyroid					X	X		X	X			
t. Peritoneal Membrane	X	X			X	X		X	X			
u.												
v.												

See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 3/31/2017

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: 3001238006

2. REASON FOR SUBMISSION

a. ☐ INITIAL REGISTRATION / LISTING
b. ☒ ANNUAL REGISTRATION / LISTING
c. ☐ CHANGE IN INFORMATION
d. ☐ INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:02-DEC-2014
DISTRICT: Dallas
PRINTED BY FDA:22-DEC-2014

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)

Community Blood Center dba Community Tissue Services

328 South Adams Street
Fort Worth, Texas 76104

a. PHONE 817-332-1898 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)

Community Blood Center dba Community Tissue Services
Attn: David M. Smith, MD
349 S. Main Street
Dayton, Ohio 45402-2715

a. PHONE 937-461-3450 EXT 3610

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME David M. Smith, MD

b. E-MAIL dsmith@cbccts.org

c. TITLE CEO d. DATE 01-DEC-2014

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions: Recover	Screen	Test	Package	Process	Store	Label	Distribute	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)
a. Bone	X	X			X	X		X	X			
b. Cartilage	X	X			X	X		X	X			
c. Cornea												
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X			X	X		X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X			X	X		X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X			X	X		X	X			
k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X			X	X		X	X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X			X	X		X	X			
q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X							X			
s. Parathyroid					X	X		X	X			
t. Peritoneal Membrane	X	X			X	X		X	X			
u.												
v.												

See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 3/31/2017

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: 3001238006

2. REASON FOR SUBMISSION

a. ☐ INITIAL REGISTRATION / LISTING
b. ☐ ANNUAL REGISTRATION / LISTING
c. ☒ CHANGE IN INFORMATION
d. ☐ INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:14-APR-2015
DISTRICT: Dallas
PRINTED BY FDA:22-JUN-2015

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)

Community Blood Center dba Community Tissue Services

328 South Adams Street
Fort Worth, Texas 76104

a. PHONE 817-332-1898 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)

Community Blood Center dba Community Tissue Services
Attn: David M. Smith, MD
349 S. Main Street
Dayton, Ohio 45402-2715

a. PHONE 937-461-3450 EXT 3610

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME David M. Smith, MD

b. E-MAIL dsmith@cbccts.org

c. TITLE CEO d. DATE 13-APR-2015

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions: Recover	Screen	Test	Package	Process	Store	Label	Distribute	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)
a. Bone	X	X			X	X		X	X			
b. Cartilage	X	X			X	X		X	X			
c. Cornea												
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X	X			X	X		X	X			
g. Heart Valve	X	X							X			
h. Ligament	X	X			X	X		X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X	X			X	X		X	X			
k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X	X			X	X		X	X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X	X			X	X		X	X			
q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X	X							X			
s. Parathyroid						X		X	X			
t. Peritoneal Membrane	X	X			X	X		X	X			
u.												
v.												

See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 3/31/2017

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: 3001238006

2. REASON FOR SUBMISSION

a. ☐ INITIAL REGISTRATION / LISTING
b. ☒ ANNUAL REGISTRATION / LISTING
c. ☐ CHANGE IN INFORMATION
d. ☐ INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:17-NOV-2015
DISTRICT: Dallas
PRINTED BY FDA:03-DEC-2015

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)

Community Blood Center dba Community Tissue Services

328 South Adams Street
Fort Worth, Texas 76104

a. PHONE 817-332-1898 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)

Community Blood Center dba Community Tissue Services
Attn: David M. Smith, MD
349 S. Main Street
Dayton, Ohio 45402-2715

a. PHONE 937-461-3450 EXT 3610

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME David M. Smith, MD

b. E-MAIL dsmith@cbccts.org

c. TITLE CEO d. DATE 16-NOV-2015

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions: Recover	Screen	Test	Package	Process	Store	Label	Distribute	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)
a. Bone						X		X	X			
b. Cartilage						X		X	X			
c. Cornea												
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia						X		X	X			
g. Heart Valve												
h. Ligament						X		X	X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium						X		X	X			
k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin						X		X	X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon						X		X	X			
q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft												
s. Peritoneal Membrane						X		X	X			
t.												
u.												
v.												