

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: 3010041508

**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-01-DEC-2017  
DISTRICT: Dallas  
PRINTED BY FDA-27-JAN-2018

See Instructions for OMB Statement FORM APPROVED/OMB No.0910-0543. Expiration Date: 6/30/2020

**PART I - ESTABLISHMENT INFORMATION**

**3. OTHER FDA REGISTRATIONS**  
a. BLOOD FDA 2830 NO. \_\_\_\_\_  
b. DEVICES FDA 2891 NO. \_\_\_\_\_  
c. DRUG FDA 2856 NO. \_\_\_\_\_

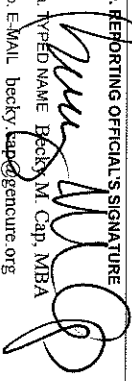
**4. PHYSICAL LOCATION** (include legal name, number and street, city, state, country, and post office code)  
GenCure  
6211 IH-10 West  
San Antonio, Texas 78201

a. PHONE 210-731-5535 EXT \_\_\_\_\_  
b.  SATELLITE RECOVERY ESTABLISHMENT  
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)  
GenCure Cord Blood Center  
Attn: Becky M. Cap, MBA  
GenCure  
6211 IH-10 West  
San Antonio, Texas 78201

a. PHONE 210-731-5586 EXT \_\_\_\_\_  
**7. ENTER CORRECTIONS TO ITEM 6** b. PHONE \_\_\_\_\_

**8. U.S. AGENT**

a. **REPORTING OFFICIAL'S SIGNATURE**  
  
a. TYPED NAME Becky M. Cap, MBA  
b. E-MAIL becky\_cap@genecure.org  
c. TITLE Chief Operating Officer  
d. DATE 01-DEC-2017

**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	12. HCT/PS REGULATED AS BIOLOGICAL DRUGS OR DRUGS	13. HCT/PS REGULATED AS	14. PROPRIETARY NAME(S)
	Recover	Screen	Test	Package	Process	Store					
a. Bone											
b. Cartilage											
c. Cornea											
d. Dura Mater											
e. Embryo											
f. Fascia											
g. Heart Valve											
h. Ligament											
i. Oocyte											
j. Pericardium											
k. Peripheral Blood Stem											
l. Sclera											
m. Semen											
n. Skin											
o. Somatic Cell Therapy Products											
p. Tendon											
q. Umbilical Cord Blood											
r. Vascular Graft											
s. Placenta											
t.											
u.											
v.											