

**1. REGISTRATION NUMBER**  
 (FDA Establishment Identifier)  
 FEB: 3010056221

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

See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543, Expiration Date: 6/30/2020  
 VALIDATION FOR FDA USE ONLY  
 VALIDATED BY FDA: 01-DEC-2017  
 DISTRICT: Dallas  
 PRINTED BY FDA: 27-JAN-2018

**PART I - ESTABLISHMENT INFORMATION**

3. OTHER FDA REGISTRATIONS  
 a. BLOOD FDA 2830 NO. \_\_\_\_\_  
 b. DEVICES FDA 2891 NO. \_\_\_\_\_  
 c. DRUG FDA 2855 NO. \_\_\_\_\_

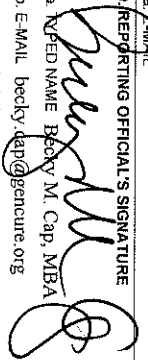
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)  
 GenCure Tissue Center  
 6211 IH-10 West  
 San Antonio, Texas 78201

5. ENTER CORRECTIONS TO ITEM 4  
 a. PHONE 210-731-5569 EXT \_\_\_\_\_  
 b.  SATELLITE RECOVERY ESTABLISHMENT  
 (MANUFACTURING ESTABLISHMENT FEI NO. \_\_\_\_\_)  
 c.  TESTING FOR MICRO-ORGANISMS ONLY

6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)  
 GenCure  
 Attn: Becky M. Cap, MBA  
 6211 IH-10 West  
 San Antonio, Texas 78201

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

8. U.S. AGENT

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

**PART II - PRODUCT INFORMATION**

Types of HCT / Ps	Establishment Functions						11 HCT/PS DESCRIBED IN 21 CFR 1271.10	11 HCT/PS REGULATED AS MEDICAL DEVICES	12 HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS	13 HCT/PS REGULATED AS DRUGS	14 PROPRIETARY NAME(S)
	Recover	Screen	Test	Package	Process	Store					
a. Bone	X	X		X	X	X	X	X	X		
b. Cartilage	X	X		X	X	X	X	X	X		
c. Cornea	X	X		X	X	X	X	X	X		
d. Dura Mater											
e. Embryo											
f. Fascia	X	X		X	X	X	X	X	X		
g. Heart Valve	X	X		X	X	X	X	X	X		
h. Ligament	X	X		X	X	X	X	X	X		
i. Oocyte											
j. Pericardium	X	X		X	X	X	X	X	X		
k. Peripheral Blood Stem											
l. Sclera											
m. Semen											
n. Skin	X	X		X	X	X	X	X	X		
o. Somatic Cell Therapy Products											
p. Tendon	X	X		X	X	X	X	X	X		
q. Umbilical Cord Blood											
r. Vascular Graft	X	X		X	X	X	X	X	X		
s. Nerve Tissue	X	X		X	X	X	X	X	X		
t. Placenta	X	X		X	X	X	X	X	X		
u. Adipose Tissue	X	X		X	X	X	X	X	X		
v.											