

**1. REGISTRATION NUMBER**  
 (FDA Establishment Identifier)  
 FEI: 3011548632

**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

**PART I - ESTABLISHMENT INFORMATION**

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2890 NO. \_\_\_\_\_

b. DEVICES FDA 2891 NO. \_\_\_\_\_

c. DRUG FDA 2896 NO. \_\_\_\_\_

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)  
 GenCure  
 1221 E. 10th St. #103  
 Weslaco, Texas 78396

5. ENTER CORRECTIONS TO ITEM 4

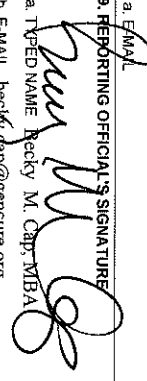
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)  
 GenCure  
 Attn: Becky M. Cap, MBA  
 6211 IH 10 West  
 San Antonio, Texas 78201

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. EMAIL becky\_cap@genecure.org  
 c. TITLE COO

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