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
(Field Establishment Identifier)
FEI: 3004732463

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:16-NOV-2011
DISTRICT: Los Angeles
PRINTED BY FDA:23-NOV-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)*
National Institute of Transplantation Laboratory
221 South Figueroa Street
Suite 510
Los Angeles, California 90012

a. PHONE 213-229-3654 EXT 150
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)*
National Institute of Transplantation Laboratory
Attn: Rose Coslett, CLS
221 South Figueroa Street
Suite 510
Los Angeles, California 90012

a. PHONE 213-229-3654 EXT 150

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Rose Coslett, CLS
b. E-MAIL rose.coslett@transplantation.com
c. TITLE Laboratory Manager d. DATE 15-NOV-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			
b. Cartilage			X						X			
c. Cornea			X						X			
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia			X						X			
g. Heart Valve			X						X			
h. Ligament			X						X			
i. Oocyte ☒ SIP ☒ Directed ☒ Anonymous			X						X			
j. Pericardium			X						X			
k. Peripheral Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera			X						X			
m. Semen ☒ SIP ☒ Directed ☒ Anonymous			X						X			
n. Skin			X						X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon			X						X			
q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft			X						X			
s.												
t.												
u.												
v.												