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: 0001174694

2. REASON FOR SUBMISSION

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

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:07-DEC-2015
DISTRICT: Baltimore
PRINTED BY FDA:16-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)

NIH Clinical Center

Dept. of Transfusion Medicine
10 Center Drive
BLDG 10 RM 1C711, MSC 1184
Bethesda, Maryland 20892-1184

a. PHONE 301-496-4506 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)

National Institutes of Health, Clinical Center
Attn: J. Wade Atkins, MS, MT(ASCP) SBB
Dept Transfusion Medicine
10 Center Drive, MSC 1184
Bldg 10, Room 1C711B
Bethesda, Maryland 20892-1184

a. PHONE 301-402-1704 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME J. Wade Atkins, MS, MT(ASCP) SBB
b. E-MAIL jatkins@cc.nih.gov
c. TITLE QA Specialist, Dept of Trans Medicine d. DATE 06-DEC-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												
b. Cartilage												
c. Cornea												
d. Dura Mater												
e. Embryo [ ] SIP [ ] Directed [ ] Anonymous												
f. Fascia												
g. Heart Valve												
h. Ligament												
i. Oocyte [ ] SIP [ ] Directed [ ] Anonymous												
j. Pericardium												
k. Peripheral Blood Stem [X] Autologous [X] Family Related [X] Allogeneic	X	X		X	X	X	X	X	X		X	
l. Sclera												
m. Semen [ ] SIP [ ] Directed [ ] Anonymous												
n. Skin												
o. Somatic Cell Therapy Products [X] Autologous [X] Family Related [X] Allogeneic	X	X		X	X	X	X	X	X		X	
p. Tendon												
q. Umbilical Cord Blood [ ] Autologous [X] Family Related [X] Allogeneic	X	X		X	X	X	X	X	X		X	
r. Vascular Graft												
s.												
t.												
u.												
v.												