See Instructions for OMB Statement

FORM APPROVED: OMB No. 0910-0543. Expiration Date: 8/31/10

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: 0001174694

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:18-DEC-2008
DISTRICT: Baltimore
PRINTED BY FDA:19-DEC-2008

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO. FEI: 0001174694

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, M.S.
Dept Transfusion Medicine
10 Center Drive, MSC 1184
Bldg 10, Room 1C711
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, M.S.

b. E-MAIL jatkins@cc.nih.gov

c. TITLE QA Specialist, Dept of Trans Medicine d. DATE 24-NOV-2008

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												
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 Cells ☒ Autologous ☒ Family Related ☒ Allogeneic	X	X		X	X	X	X	X	X		X	
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin												
o. Somatic Cell Therapy Products ☒ Autologous ☒ Family Related ☒ Allogeneic	X	X		X	X	X	X	X	X		X	
p. Tendon												
q. Umbilical Cord Blood Stem Cells ☐ Autologous ☒ Family Related ☒ Allogeneic	X	X		X	X	X	X	X	X		X	
r. Vascular Graft												
s.												
t.												
u.												
v.												