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: 3005287828

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:20-NOV-2011
DISTRICT: Philadelphia
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)*

Fairfax Cryobank - Philadelphia
3401 Market Street
Suite 205
Philadelphia, Pennsylvania 19104

a. PHONE 215-386-1977 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)*

Fairfax Cryobank
Attn: Megan Taylor
3015 Williams Drive
Suite 110
Fairfax, Virginia 22031

a. PHONE 800-338-8407 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE Megan Taylor

a. TYPED NAME Megan Taylor

b. E-MAIL mtaylor@givf.com

c. TITLE Document Administrator d. DATE 19-NOV-2011

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps		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						X	X	X	X			
f. Fascia													
g. Heart Valve													
h. Ligament													
i. Oocyte	☒ SIP ☒ Directed ☒ Anonymous						X	X	X	X			
j. Pericardium													
k. Peripheral Blood Stem Cells	☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera													
m. Semen	☒ SIP ☒ Directed ☒ Anonymous	X	X		X	X	X	X	X	X			
n. Skin													
o. Somatic Cell Therapy Products	☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon													
q. Umbilical Cord Blood Stem Cells	☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft													
s. Testicular Tissue							X	X	X	X			
t.													
u.													
v.													