

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: 3004731690

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:20-NOV-2011
 DISTRICT: Baltimore
 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
 3015 Williams Drive
 Suite 110
 Fairfax, Virginia 22031

a. PHONE 800-338-8407 EXT _____
 b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEINO. _____)
 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

 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	Establishment Functions						14. PROPRIETARY NAME(S)										
	Recover	Screen	Test	Package	Process	Store		Label	Distribute								
a. Bone																	
b. Cartilage																	
c. Cornea																	
d. Dura Mater																	
e. Embryo <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input type="checkbox"/> Anonymous						X	X	X	X	X	X	X	X	X			
f. Fascia																	
g. Heart Valve																	
h. Ligament																	
i. Oocyte <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous						X	X	X	X	X	X	X	X	X			
j. Pericardium																	
k. Peripheral Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																	
l. Solera																	
m. Semen <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous						X	X	X	X	X	X	X	X	X			
n. Skin																	
o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																	
p. Tendon																	
q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																	
r. Vascular Graft																	
s. Testicular Tissue										X	X	X	X	X			
t.																	
u.																	
v.																	