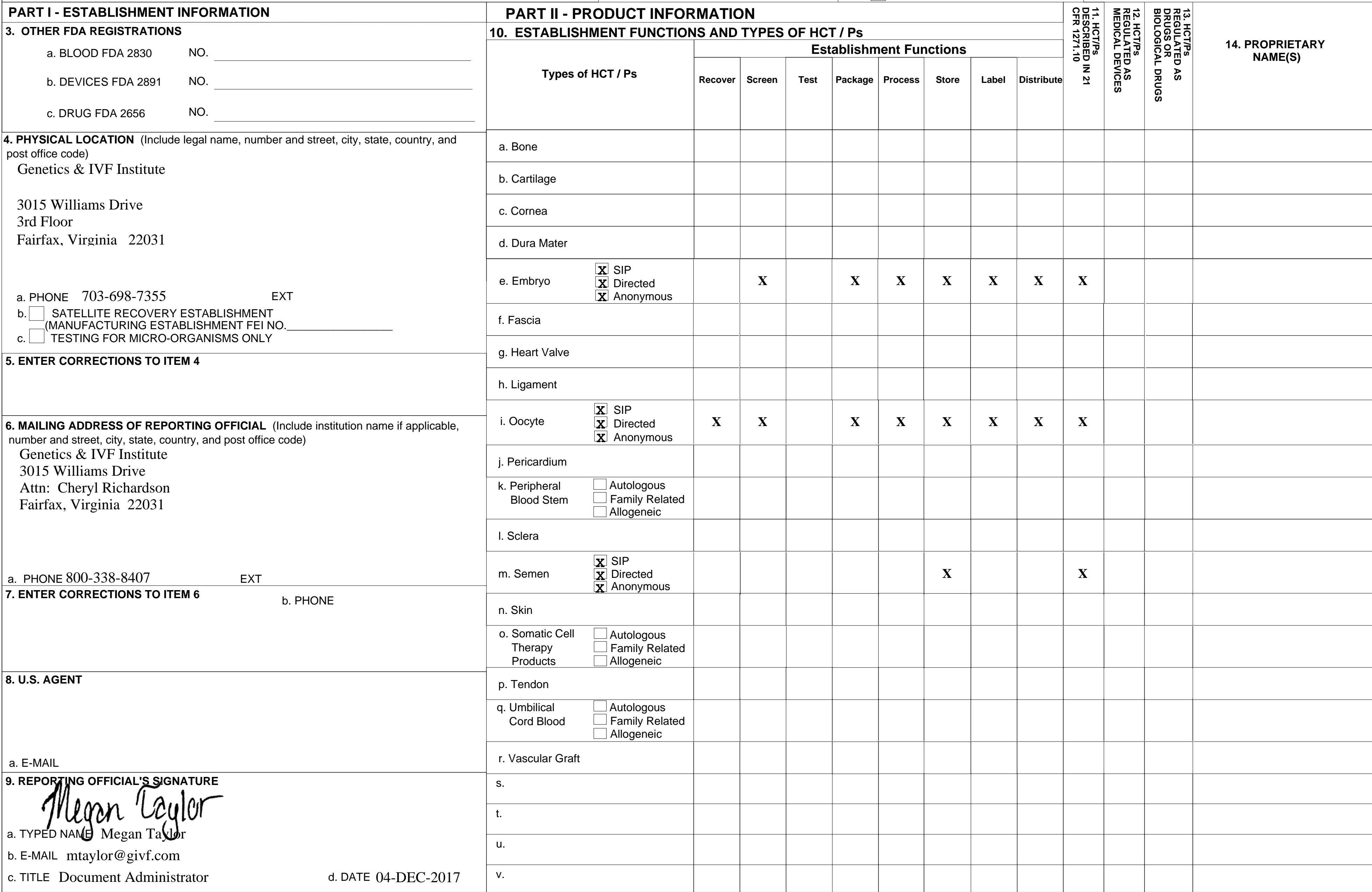

See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 6/30/2020

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: 3003140045

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:04-DEC-2017
DISTRICT: Baltimore
PRINTED BY FDA:27-JAN-2018

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)
Genetics & IVF Institute

3015 Williams Drive
3rd Floor
Fairfax, Virginia 22031

a. PHONE 703-698-7355 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)
Genetics & IVF Institute
3015 Williams Drive
Attn: Cheryl Richardson
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 04-DEC-2017

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

FORM FDA - 3356 (7/17)