

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: 3002719998

2. REASON FOR SUBMISSION
a. INITIAL REGISTRATION / LISTING
b. ANNUAL REGISTRATION / LISTING
c. CHANGE IN INFORMATION
d. INACTIVE

See Instructions for OMB Statement
FORM APPROVED - OMB No. 0910-0543, Expiration Date: 1/31/14
VALIDATION - FOR FDA USE ONLY
VALIDATED BY FDA-05-OCT-2011
DISTRICT: Florida
PRINTED BY FDA-24-OCT-2011

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2830 NO. _____
b. DEVICES FDA 2891 NO. FEI: 3002719998
c. DRUG FDA 2696 NO. _____

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)
R11 Biologics, Inc.
11621 Research Circle
Alachua, Florida 32615

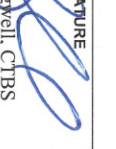
a. PHONE 386-418-8888 EXT 4564
b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____)
c. TESTING FOR MICRO-ORGANISMS ONLY

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)
RTI Biologics, Inc.
Attn: Cheryl L. Bagwell, CTBS
11621 Research Circle
Alachua, Florida 32615

a. PHONE 386-418-8888 EXT 4564
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____

8. U.S. AGENT

a. E-MAIL

b. E-MAIL bbagwell@rtix.com
c. TITLE Compliance Manager
d. DATE 04-OCT-2011

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / PS

Types of HCT / PS	Establishment Functions						11. HCT/PS RECOVERED IN 21	12. HCT/PS REGULATED AS MEDICAL DEVICES	13. HCT/PS REGULATED AS BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
	Recover	Screen	Test	Package	Process	Store				
a. Bone	X			X	X	X	X	X	X	
b. Cartilage	X			X	X	X	X	X	X	
c. Cornea	X								X	
d. Dura Mater										
e. Embryo										
f. Fascia	X			X	X	X	X	X	X	
g. Heart Valve									D	
h. Ligament	X			X	X	X	X	X	X	
i. Oocyte										
j. Pericardium	X			X	X	X	X	X	X	
k. Peripheral Blood Stem										
l. Sclera	X			X	X	X	X	X	X	
m. Semen										
n. Skin	X			X	X	X	X	X	X	
o. Somatic Cell Therapy Products										
p. Tendon	X			X	X	X	X	X	X	
q. Umbilical Cord Blood										
r. Vascular Graft	X								X	
s.										
t.										
u.										
v.										