

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: 3003103596

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:23-DEC-2016
DISTRICT: Detroit
PRINTED BY FDA:03-JAN-2017

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)

Indiana Organ Procurement Organization dba Indiana Donor Network

3760 Guion Road
Indianapolis, Indiana 46222

- a. PHONE 317-685-0389 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)

Indiana Organ Procurement Organization dba Indiana Donor Network
Attn: Erin S. Seaverns, RN
3760 Guion Road
Indianapolis, Indiana 46222

- a. PHONE 317-685-0389 EXT

7. ENTER CORRECTIONS TO ITEM 6

b. PHONE

8. U.S. AGENT

- a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE



- a. TYPED NAME Erin S. Seaverns, RN

- b. E-MAIL eseaverns@indonornetwork.org

- c. TITLE Manager, Regulatory Compliance

- d. DATE 22-DEC-2016

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	X	X		X		X	X	X				
b. Cartilage	X	X		X		X	X	X				
c. Cornea	X	X		X		X	X	X				
d. Dura Mater												
e. Embryo												
	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
f. Fascia	X	X		X		X	X	X				
g. Heart Valve	X	X		X		X	X	X				
h. Ligament	X	X		X		X	X	X				
i. Oocyte												
	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
j. Pericardium	X	X		X		X	X	X				
k. Peripheral Blood Stem												
	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
l. Sclera												
m. Semen												
	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
n. Skin	X	X		X		X	X	X				
o. Somatic Cell Therapy Products												
	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
p. Tendon	X	X		X		X	X	X				
q. Umbilical Cord Blood												
	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
r. Vascular Graft	X	X		X		X	X	X				
s.												
t.												
u.												
v.												