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 **DESCRIBED IN 21 CFR 1271.10**

FEI: 3003934255

Other FDA Registrations:

Drugs:

Blood: Devices: Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2024 Last Registration Receipt Date: 12/04/2023 Summary Report Print Date: 12/15/2023

Legal Name and Location:

Dana - Farber Cancer Institute Connell & O'Reilly Families' Cell Manipulation Core Facility 450 Brookline Ave SM12

Boston, Massachusetts 02215

USA

Phone: 617-694-1866

Ext.:

Reporting Official:

Jerome Ritz. Director Connell & O'Reilly Families' Cell Manipulation Core Facility 450 Brookline Ave Boston, Massachusetts 02215

Phone: 617-632-3465 Ext. jerome_ritz@dfci.harvard.edu Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only: No

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

No

		Establishment Functions										
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane												
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis	Autologous, Family Related				Х	X	Х	Х	Х			
HPC Cord Blood	Family Related						Х	Х	Х			
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells	Autologous, Family Related				Х	Х	Х	Х	Х			
Peritoneal Membrane												
Sclera												
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information:	No additional information provided

Proprietary Name(s):

FEI: 3003934255 Legal Name: Dana - Farber Cancer Institute