Source Plasma Donation Center (SPDC) Program
Wadsworth Center
New York State Department of Health Empire State Plaza Albany, NY 12237
www.wadsworth.org/regulatory/plasma

Notification of Change in Responsible Physician

Notification of a change in Responsible Physician must be made **within 60 days** of the effective date to New York State Department of Health.

PLEASE RETURN THIS COMPLETED AND SIGNED FORM
AND A COPY OF THE PHYSICIAN LICENSE REGISTRATION BY ONE METHOD ONLY:
Fax (518) 449-6901 or email plasma@health.ny.gov.

SOURCE PLASMA DONATION CENTER INFORMATION		
SPDC PFI Number: PA _____ _____		
SPDC Name:		
SPDC Address:		
City:	State:	ZIP Code:
FORMER Responsible Physician Name:		
Effective Date of Change:		

NEW RESPONSIBLE PHYSICIAN INFORMATION: Complete this section in its entirety for the NEW individual.			
First Name:	M.I.:	Last Name:	☐ M.D. ☐ D.O.
Effective Date:	Average Weekly On-site Presence (hours):		
New York State (NYS) Professional License Number (6 digit):			
INCLUDE COPY OF CURRENT NYS PHYSICIAN LICENSE REGISTRATION WITH THIS FORM			
Home Address:			
City:	State:	ZIP Code:	
Work E-mail Address:		Work Phone Number:	

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RESPONSIBLE PHYSICIAN TRAINING

Describe the training that qualifies the physician to function in the role of a responsible physician for source plasma donation center.

Per 21 CFR (Code of Federal Regulation) 630.3: This individual must be trained and qualified to direct and control personnel and relevant procedures concerning the determination of: donor eligibility; collection of blood and blood components; the immunization of the donor; and the return of red blood cells or other blood components to the donor during collection of blood components by apheresis.

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CERTIFICATION:

I understand that by signing this Source Plasma Donation Center Change of Laboratory Director form:

1. Subpart 58-4 of Title 10 (Health) of the Official Compilation of Codes, Rules, and Regulations of the State of New York (NYCRR) establishes regulatory requirements for source plasma donation centers. The source plasma donation center responsible physician and laboratory director shall be jointly responsible for ensuring compliance with the Subpart. The source plasma donation center responsible physician shall be responsible for ensuring compliance with the Code of Federal Regulation (CFR), Title 21, Parts 630 and 640. The laboratory director shall be responsible for ensuring compliance with CFR, Title 42, Part 493.
2. I agree to any investigation made by the Department of Health (Department) to verify or confirm the information provided herein or adjunctive to this application, and any investigation in connection with the registration, a complaint or incident report made known to the Department. Further, I understand that, should this application or my status be investigated at any time, I agree to cooperate in such an investigation and provide the Department with immediate access to all facilities, equipment, records, and personnel as required by the Department to determine compliance with this subdivision.
3. I attest that the information I have given the Department is true and correct, that I have read the relevant rules and regulations, and I accept responsibility for the activities performed at the applying facility.
4. I understand that if the source plasma donation center wishes to perform testing other than hematocrit or total protein for donor eligibility, including all other donor eligibility testing and mandated infectious disease testing on the donated plasma, a New York Clinical Laboratory Permit is required. I further understand that the collection, storage, processing or distribution of a blood component for any purpose other than use as source material for manufacture requires a New York Blood Bank Permit.

Wet signature only. Signature stamps will not be accepted.

Date:	Signature, NEW Responsible Physician:	Name, NEW Responsible Physician (Print):
Date:	Signature, Owner/Representative:	Name, Owner/Representative (Print):