NEW YORK STATE DEPARTMENT OF HEALTH
Wadsworth Center

Source Plasma Donation Center Initial Registration Application

Clinical Laboratory Evaluation Program/Plasma
Empire State Plaza
Albany, New York 12237
E-mail: plasma@health.ny.gov
Web: www.wadsworth.org/regulatory/plasma

For Office Use Only ☐ I ☐ R
Rec'd
Fee No.
PFI
CLIA No.

Please follow the instructions carefully since the submission of an incomplete application will delay the processing and issuance of the registration. Mail the entire application package (see steps 1-3 below) to the address above.

NOTE:

1) Fill out this application form. Print and obtain required signatures. Attach hard copies of requested additional documentation as instructed in each section.
2) Fill out and attach Form DOH-5790: Statement of Disclosure of Ownership, Controlling Interest, Corporate Membership, Management (Operator).
3) Enclose a **$600.00 application fee payment**. Your check or money order must be made payable to: New York State Department of Health. This fee is nonrefundable.

1 – Opening Date (projected)

Date:

2 – General Information

Center	Name (Limited to 70 characters)		
	Address (Physical Location)		
	Street/Suite		
	City	State	ZIP code
	County/Borough		
	Mailing Address (If different from physical location)		
	Attention (name and title)		
	City	State	ZIP code
	Email Address		
	Phone Number	Fax Number	
	Federal Employer ID Number (FEIN)		
	FDA Establishment Identification Number (FEI)		
	Note, FEIN and FEI are two **different** numbers		

Hours of Operation Please specify AM or PM

	Mon	Tue	Wed	Thu	Fri	Sat	Sun
From							
To							

Plasma Donation Center Name: ZIP Code:

3 – Registration Point of Contact

- The contact person responsible for the overall registration process of the source plasma donation center

Contact Person	Name
	Position
	Email address
	Phone number

4 – Donation Center Responsible Physician

Identify the individual who meets the federal requirements as the qualified physician who is responsible for source plasma collection procedures.

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.

- If so qualified, the responsible physician and the laboratory director may be the same person.

Responsible Physician	Name
	Position
	Email address
	Phone number
	NYS Professional License Number (and **attach copy of current registration**)
	Average weekly on-site presence (hours)
	Describe the training that qualifies the physician to function in the role of a responsible physician for source plasma donation center.

5 – Laboratory Director

Identify the individual who meets the federal requirements to direct the testing for hematocrit and moderate complexity total protein. Laboratory director is responsible for the overall operation and administration of the laboratory, in accordance with 42 CFR 493.1407. Laboratory director may direct no more than a total combination of five high and moderate complexity laboratories, including laboratories outside of New York State (NYS).

Laboratory Director	Name
	Home address
	Email address
	Phone number
	Average weekly on-site presence (hours)

Laboratory Director Qualification (check appropriate box and attach supporting documents as indicated):

☐ **Doctor of Medicine or Osteopathy in NYS,** and: 1) certified in Anatomic or Clinical Pathology (or both) or 2) possess qualifications that are equivalent to those required for board certification

*__Attach__ copy of NYS license registration **AND** board certification and board certification renewal (as appropriate); or current eligibility for board certification in Anatomic or Clinical pathology

☐ **Doctor of Medicine, Osteopathy, Podiatric Medicine in NYS**, and have at least one year training or experience, or both, in non-waived testing in the specialty of chemistry

*__Attach__ copy of NYS license registration **AND** memorandum attesting to above experience, from the laboratory director where experience was acquired (include CLIA number and types of tests)

☐ **Doctor of Medicine, Osteopathy, Podiatric Medicine in NYS,** and have at least: 20 hours of continued medical education (CME) in laboratory director responsibilities or 20 hours of training in laboratory director responsibilities acquired during medical residency/fellowship training

*__Attach__ copy of NYS license registration **AND** proof of 20 hours acquired via CME or residency/fellowship training

☐ **Earned a doctoral degree in chemical, physical, biological, or clinical laboratory science** from an accredited institution, and be certified by: American Board of Medical Microbiology, American Board of Clinical Chemistry, or American Board of Laboratory Immunology

*__Attach__ copy of doctorate diploma (and transcript if degree does not list field) **AND** current board certification

☐ **Earned a doctoral degree in chemical, physical, biological, or clinical laboratory science** from an accredited institution, and have at least one year experience directing or supervising non-waived testing

*__Attach__ copy of doctoral degree (and transcript if degree does not list field) **AND** memorandum attesting to above experience, from the laboratory director where experience was acquired (include CLIA number and types of tests)

☐ **Earned a master's degree in a chemical, physical, biological, or clinical laboratory science, or medical technology** from an accredited institution, and have at least one year training or experience (or both) in non-waived testing, and in addition have at least one separate year of supervisory laboratory experience in non-waived testing

*__Attach__ a copy of master's degree (and transcript if degree does not list major) AND memorandum attesting to above experience, from the laboratory director where experience was acquired (include CLIA number and types of tests)

☐ **Earned a bachelor's degree in a chemical, physical, biological, or clinical laboratory science, or medical technology** from an accredited institution, and have at least two years training or experience (or both) in non-waived testing, and in addition have at least two separate years of supervisory laboratory experience in non-waived testing

*__Attach__ a copy of bachelor's degree (and transcript if degree does not list major) **AND** memorandum attesting to above experience, from the laboratory director where experience was acquired (include CLIA number and types of tests)

6 – Laboratory Technical Consultant(s)

Identify the individual(s) who is/are the laboratory technical consultant(s) and check box indicating their qualifications. The technical consultant may be the laboratory director, if so qualified per below. The technical consultant(s) is/are responsible for the technical and scientific oversight of the laboratory, in accordance with 42 CFR 493.1413. There may be more than one technical consultant.

- If there is more than one technical consultant, please click Add Page button below. A duplicate page will be added to the end of the document

☐ **If the laboratory director serves as the technical consultant, check this box.**

Name of Technical Consultant:

Technical Consultant Qualification (check appropriate box and attach supporting documents as indicated):

☐ **Doctor of Medicine or Osteopathy in NYS,** and certified in Anatomic or Clinical Pathology (or both) or possess qualifications that are equivalent to those required for board certification

*__Attach copy__ of NYS license registration **AND** board certification and board certification renewal (as appropriate); or current eligibility for board certification in Anatomic or Clinical pathology

☐ **Doctor of Medicine, Osteopathy, Podiatric Medicine in NYS,** and have at least one year training or experience, or both, in non-waived testing in the specialty of chemistry

*__Attach copy__ of NYS license registration **AND** memorandum attesting to above experience, from the laboratory director where experience was acquired (include CLIA number and types of tests)

☐ **Earned a doctoral degree or master's degree in chemical, physical, biological, or clinical laboratory science or medical technology** from an accredited institution, and have at least one year laboratory training or experience, or both, in non-waived testing in the specialty of chemistry

*__Attach copy__ of doctoral or master's diploma; transcripts if diploma does not state major; and memorandum attesting to above experience, from the laboratory director where experience was acquired (include CLIA number and types of tests)

☐ **Earned a bachelor's degree in a chemical, physical, biological, or clinical laboratory science, or medical technology** from an accredited institution, and have at least two years training or experience (or both) in non-waived testing in the specialty of chemistry

*__Attach copy__ of bachelor's diploma; transcripts if diploma does not state major; and memorandum attesting to above experience, from the laboratory director where experience was acquired (include CLIA number and types of tests)

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7 – Laboratory Clinical Consultant(s)

Identify the individual(s) who is/are the laboratory clinical consultant(s), and check box stating their qualifications. The clinical consultant may be the laboratory director, if so qualified per below. The clinical consultant(s) provide(s) consultation regarding the appropriateness of the testing ordered, and interpretation of test results, in accordance with 42 CFR 493.1419. There may be more than one clinical consultant.

- If there is more than one technical consultant, please click Add Page button below. A duplicate page will be added to the end of the document.

☐ **If the laboratory director serves as the clinical consultant, check this box.**

☐ **If the responsible physician serves as the clinical consultant, check this box.**

Name of Clinical Consultant:

Clinical Consultant Qualification (check appropriate box and attach supporting documents as indicated):

☐ **Doctor of Medicine or Osteopathy in NYS**

*__Attach copy__ of NYS license registration **AND** board certification and board certification renewal (as appropriate); or current eligibility for board certification in Anatomic or Clinical pathology

☐ **Earned a doctoral degree in chemical, physical, biological, or clinical laboratory science** from an accredited institution, and be certified by American Board of Clinical Chemistry, American Board of Bioanalysis, or American Board of Medical Laboratory Immunology

*__Attach copy__ of 1) doctorate diploma; 2) transcripts if diploma does not state degree field; and 3) copy of current board certification

8 – Physician Substitutes

The source plasma donation center responsible physician may delegate certain duties to a "physician substitute."

In New York State, the role of source plasma donation center physician substitute is within the scope of practice for the below categories of licensed health care workers. Identify the number of individuals employed as physician substitutes next to their qualifications.

- A copy of the current NYS professional license registration certificate and current CPR training certificate must be available for inspection by the Department.

License Held	Number of Personnel
Physician Assistant (PA)	
Nurse Practitioners (NP)	
Registered Nurse (RN)	
Licensed Practical Nurse (LPN)	

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9 – Laboratory Testing Personnel

Identify the number of individuals employed as testing personnel, with their level of qualification. Testing personnel are responsible for specimen processing, test performance, and test result reporting, in accordance with 42 CFR 493.1425.

- A copy of a diploma or military certification, for all those other than MD/DO, must be available in the laboratory for inspection by the Department. Transcripts must also be provided if degree does not list post high school major.

Degree	Number of Testing Personnel
MD or DO with NY professional license	
PhD: biological, chemical, physical, clinical lab science; medical laboratory technology	
Master's: biological, chemical, physical, clinical lab science; medical laboratory technology	
Bachelor's: biological, chemical, physical, clinical lab science; medical laboratory technology	
Associate's: biological, chemical, physical, clinical lab science; medical laboratory technology	
Held military occupation as Medical Laboratory Specialist	
Hold high school degree	

10 – Laboratory Testing Devices

Indicate the specific testing devices used for donor eligibility testing and the estimated annual testing volume (i.e., number of times test is performed).

- Do not include number of tests run for proficiency testing, controls, or quality assurance.

Hematocrit	
Manufacturer	
Model	
Annual Testing Volume (estimate)	
Total Protein	
Manufacturer	
Model	
Annual Testing Volume (estimate)	

Plasma Donation Center Name: ZIP Code:

11 – Certification and Attestation

I understand that by signing this Source Plasma Donation Center application 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. Registration may be denied, suspended, revoked or annulled by the Department of Health (Department) upon a determination that a source plasma donation center registrant: (i) failed to comply with the requirements in regulation; (ii) intentionally provided false or misleading information to the Department relating to registration; (iii) provided services that constitute an unwarranted risk to human health; or (iv) has demonstrated incompetence or shown consistent errors in the performance of examinations or procedures.
3. Source plasma donation center registrants shall advise the Department of any change in the registrant's: center name, location, ownership (direct or indirect), operator, responsible physician or laboratory director within thirty (30) days of such change.
4. I agree to any investigation made by the 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.
5. I attest that the information I have given the Department of Health as a basis for obtaining a Source Plasma Donation Center Registration is true and correct, that I have read the relevant rules and regulations, and I accept rresponsibility for the activities performed at the applying facility.
6. 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 are not accepted.	
Print Name of Responsible Physician	
Signature of Responsible Physician	Date
Print Name of Laboratory Director	
Signature or Laboratory Director	Date
Print Name of Direct Owner Representative	
Signature of Direct Owner Representative	Date

Include with submission:

- **$600.00 check payable to the New York State Department of Health**
- **Completed Form DOH-5790: Statement of Disclosure of Ownership, Controlling Interest, Corporate Membership, Management (Operator)**