New Jersey Department of Health
Clinical Laboratory Improvement Service
PO Box 361
Trenton, NJ 08625-0361

APPLICATION FOR LICENSURE OF A BLOOD BANK
(Under the Provisions of N.J.S.A. 26:2A et seq.)

NOTICE TO ALL APPLICANTS FOR A BLOOD BANK LICENSE

The signed and notarized Application for a Blood Bank License, under the provisions of N.J.S.A. 26:2A et seq., and all requested attachments, must be completed in full and returned with the appropriate fee. Fees are non-refundable and incomplete applications will not be processed if information regarding ownership and director is omitted. All applicable sections of this application must be completed.

Checks or money orders should be made payable to the *"**New Jersey Department of Health**"* and include the Blood Bank Code on the check. You may also make your payment using the electronic payment link on the Clinical Laboratory Improvement Services website (http://nj.gov/health/phel/clis.shtml). Please include a copy of the Department of Health Payment Confirmation with the application.

The application for licensure and all requested attachments should be mailed to:

Regular Mail (US Postal Service)
New Jersey Department of Health
PHEL/Clinical Laboratory Improvement Service
Attention: Blood Bank Program
P.O. Box 361
Trenton, NJ 08625-0361

Overnight Delivery (FedEx, UPS)
New Jersey Department of Health
PHEL/Clinical Laboratory Improvement Service
Attention: Blood Bank Program
Public Health, Environmental and Agricultural Laboratory
3 Schwarzkopf Drive
Ewing, NJ 08628

INITIAL LICENSURE (Check appropriate box on top of page one)

Application for an initial license to conduct a blood bank shall be made on forms provided for that purpose by the New Jersey Department of Health.

Each license to operate a blood bank will indicate those services which the blood bank will be authorized to perform.

A license issued under these regulations IS NOT transferable.

A new license shall be obtained whenever the name or location of a blood bank is changed. **The department must be notified by certified mail 30 days prior to such changes, and whenever the ownership, corporate structure, director, and/or services of a blood bank change.**

The license shall be conspicuously displayed by the licensee on the blood bank premises.

ANNUAL RENEWAL OF LICENSURE (Check appropriate box on top of page one)

All blood bank licenses shall be issued on or before January 1 of each calendar year and shall expire on December 31 of each calendar year.

The Department of Health will provide applications for licensure renewal on or before October 1 of each year to be properly completed and returned to the Department, together with the appropriate licensure renewal fee, **on or before the succeeding November 10.** The department will mail license renewals to blood banks not later than January 1 of the licensure year.

Important: Please type or print with ballpoint pen when completing application.

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PO Box 361
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APPLICATION FOR A BLOOD BANK LICENSE

Important: *Please type or print with ballpoint pen when completing application.*

Type of Application:
☐ Initial
☐ Renewal
Fee: **$**
Refer to Attached Fee Schedule and Invoice.

FOR STATE USE ONLY			
Date Mailed	Date Received	☐ Approved ☐ Denied ☐ Other	
Received By	Check Number	Amount	Check Date

Name and Address of Facility	Name of Person Completing Application
	Telephone Number ( )
	Fax Number ( )
Blood Bank Code	Email Address

Type of Blood Bank *(Check appropriate type)*

- ☐ Hospital Transfusion Service
- ☐ Hospital Transfusion/Donor Service
- ☐ Donor Center
- ☐ Perioperative Autologous Blood Collection/Administration
- ☐ Plasmapheresis Center
- ☐ Blood Storage Only
- ☐ Emergency Transfusion Only (Ambulatory Surgery Center)
- ☐ Industrial Manufacturer
- ☐ Broker
- ☐ Donor Center - Located Out of State
- ☐ Transfusion Only (Home Care Agency, Physician's Office, Dialysis Center, or Other Entity Licensed to Perform Transfusions Only)
- ☐ Hematopoietic Progenitor Cells (HPC)
- ☐ Cord Blood
- ☐ Collection Site
- ☐ Therapeutic Phlebotomy
- ☐ Other (Specify): _____

Name of Authorized Agent/Owner	Telephone Number ( )
Address	

Type of Ownership
☐ Individual ☐ Partnership* ☐ Corporate* ☐ Gov't Type: ☐ State ☐ County ☐ Municipal

Name of Owner/Corporate Director	☐ Owner ☐ Corporate Director
Address	

***Attach list of officers and/or corporate structure of ownership.

APPLICATION FOR A BLOOD BANK LICENSE, Continued

Name of Blood Bank Director	Telephone Number
Address	Email Address

Does the Blood Bank Director hold a license to practice medicine in New Jersey?

☐ Yes ☐ No

N. J. Medical License Number: _____

Date Issued: _____

Length of experience in operating a Blood Bank since licensed to practice medicine? _____

Blood Bank Director's Time on Premises [Indicate specific hours each day (e.g., 9 - 5)]:

☐ Full Time ☐ Part Time

Mon _____ Tue _____ Wed _____ Thu _____ Fri _____ Sat _____ Sun _____

Does Director serve as Director or Co-Director for blood banks or laboratories at other locations?

☐ Yes ☐ No

If yes, give names and addresses of other blood banks or laboratories, whether or not located in New Jersey.
Indicate specific hours for each day (e.g., 9 - 5):

Name: _____

Address: _____

Mon _____ Tue _____ Wed _____ Thu _____ Fri _____ Sat _____ Sun _____

Name: _____

Address: _____

Mon _____ Tue _____ Wed _____ Thu _____ Fri _____ Sat _____ Sun _____

Name of Blood Bank Co-Director	Telephone Number
Address	

Does the Blood Bank Co-Director hold a license to practice medicine in New Jersey?

☐ Yes ☐ No

N. J. Medical License Number: _____

Date Issued: _____

Length of experience in operating a Blood Bank since licensed to practice medicine? _____

Blood Bank Co-Director's Time on Premises [Indicate specific hours each day (e.g., 9 - 5)]:

☐ Full Time ☐ Part Time

Mon _____ Tue _____ Wed _____ Thu _____ Fri _____ Sat _____ Sun _____

APPLICATION FOR A BLOOD BANK LICENSE, Continued

SERVICES OFFERED

Check the services actually performed in your blood bank. This section will be used to determine the services licensed at your facility. Before initiating those services marked with an asterisk (*), written approval must be received from the Department.

- ☐ Transfusion Services*
  - ☐ On-Site*
  - ☐ Home*
- ☐ Transfusion Only*
  - ☐ On Site*
  - ☐ Mobile Site*
  - ☐ Home*
  - ☐ Emergency*
- ☐ Collection Services*
  - ☐ On Site*
  - ☐ Mobile Site*
  - ☐ Allogeneic*
  - ☐ Autologous*
  - ☐ Directed*
  - ☐ Therapeutic Phlebotomy*
  - ☐ Hemapheresis*
    - ☐ Plasmapheresis*
    - ☐ Leukapheresis*
    - ☐ Plateletpheresis*
    - ☐ Cytapheresis*
    - ☐ Therapeutic*
  - ☐ Cord Blood*
  - ☐ Hematopoietic Progenitor Cells (HPC)*
- ☐ Collection Services* (continued)
  - ☐ Double Red Cell
  - ☐ Perioperative Autologous Blood Collection/Administration*
- ☐ Processing (Routine)
  - ☐ ABO Group
  - ☐ Rh Type
  - ☐ Antibody Detection
  - ☐ Antibody Identification
  - ☐ Crossmatch
  - ☐ Antiglobulin Test
- ☐ Processing (Special)
  - ☐ HBsAg
  - ☐ Anti-HBc
  - ☐ Anti-HCV
  - ☐ Anti-HIV-1/2
  - ☐ Anti-HTLV-I/II
  - ☐ Syphilis
  - ☐ HBV RNA
  - ☐ HCV RNA
  - ☐ HIV-1 RNA
  - ☐ WNV RNA
  - ☐ Trypanosoma cruzi
- ☐ Processing [Hematopoietic Progenitor Cells (HPC)]*
- ☐ Storage [Hematopoietic Progenitor Cells (HPC)]*
- ☐ Component Preparation
  - ☐ Red Blood Cells (RBC)
  - ☐ Frozen RBC
  - ☐ Washed RBC
  - ☐ RBC Leukocytes Reduced
  - ☐ Fresh Frozen Plasma
  - ☐ Platelets
  - ☐ Platelets Leukocytes Reduced
  - ☐ Cryoprecipitated AHF
  - ☐ Leukocytes
  - ☐ Irradiated Products
  - ☐ Plasma Frozen within 24 Hours after Phlebotomy
  - ☐ Plasma Cryoprecipitate Reduced
  - ☐ Thawed Plasma
  - ☐ Recovered Plasma
- ☐ Manufacturer*
- ☐ Ambulatory Surgery Center
- ☐ Dialysis Service
- ☐ Plasmapheresis Center*
- ☐ Broker*

If Umbilical Cord and Stem Cell Collections are provided at your facility by another entity, list below the name and address of the entity:

Name: _____

Address: _____

NOTE: Must be licensed as a blood bank in New Jersey to be allowed to offer services at your facility.

List below all Blood Banks or Laboratories to which work not performed on the premises is referred:

Name: _____

Address: _____

Name: _____

Address: _____

Is Plasma recovered at your facility?

☐ Yes ☐ No

Distribution of Recovered Plasma (Broker must be licensed in New Jersey):

Name: _____

Address: _____

SITES FOR COLLECTION OF BLOOD

Check the column for the services your blood bank provides:

☐ Mobile Units (Moveable unit used to collect blood from donors not at blood bank site).
List the name and/or other method of identifying each of your mobile units in New Jersey.

_____

_____

☐ Stationary Collection Sites (Collection Site License Required) (A site for a blood bank permanently located at another facility which is used for the collection of blood and/or blood components.)
List the name and location of each of your sites in New Jersey.

_____

_____

APPLICATION FOR A BLOOD BANK LICENSE, Continued

BLOOD BANK PERSONNEL

List all personnel who are serving as blood bank director, co-director, blood bank supervisor, general laboratory supervisor, phlebotomy supervisor, blood collection supervisor, technical supervisor, technologist, technician, phlebotomist, or transfusionist in the blood bank. Use the codes below to indicate the function of each employee.

Name (Last, First, MI)	Degree	Time		Function As										STATE USE ONLY
		Full	Part	D/CO	BB/S	GL/S	P/S	BC/S	T/S	T	TN	P	TR	

Codes:

D/CO - Blood Bank Director/Co-Director
BB/S – Blood Bank Supervisor
GL/S - General Laboratory Supervisor
P/S - Phlebotomy Supervisor
T/S - Technical Supervisor
BC/S - Blood Collection Supervisor
T - Technologist
TN - Technician
P - Phlebotomist
TR - Transfusionist

APPLICATION FOR A BLOOD BANK LICENSE, Continued

PROFESSIONAL ORGANIZATIONS

Is your Blood Bank a member of any professional organization?

☐ Yes ☐ No

If yes, list the name(s) of the organization(s) and the type of membership:

_____ _____

_____ _____

_____ _____

COMPUTER USE

Is a computer system in use in the blood bank?

☐ Yes ☐ No

If yes, specify the computer system and software used:

_____

_____

Was the system developed specifically for blood bank use?

☐ Yes ☐ No

Is the computer system shared by other departments, shared regionally, or part of a complex network?

☐ Yes ☐ No

Check the areas that are computerized:

- ☐ Donor Registration
- ☐ Labeling
- ☐ Inventory Control
- ☐ Component Preparation
- ☐ Distribution and/or Issue
- ☐ Required Recipient Testing
- ☐ Blood/Component Orders
- ☐ Required Donor Testing
- ☐ Transfusion Records
- ☐ Compatibility/Crossmatch
- ☐ Archives (Patient Testing Records, Transfusion History)

Does the computer perform control functions for the release of blood/blood components to inventory and for transfusion?

☐ Yes ☐ No

Is the computer used as the primary method of record keeping?

☐ Yes ☐ No

If yes, does it provide an automatic method that documents changes to verified records?

☐ Yes ☐ No

APPLICATION FOR A BLOOD BANK LICENSE, Continued

I/We agree to assume complete responsibility for all business to be carried on in the premises for which I/we am/are making this application for a License, and I/we further agree that all of said business conducted in said premises will be carried on at all times in full compliance with N.J.S.A. 26:2a-2 et seq. and N.J.A.C. 8:8-1 et seq., as well as all Federal, State and municipal laws, rules, ordinances, and zoning regulations thereunto pertaining. The prescribed fee (refer to Fee Schedule and Invoice) payable to the New Jersey Department of Health is forwarded herewith.

We the undersigned certify that the information given on this application and on the accompanying attachments is true, correct and complete as of this date and that notification, by certified mail, of any change(s) will be made within 14 days of such change(s). The blood bank shall perform only those services related to the above chapters, for which they specifically request and receive licensure. In the case of new services, written approval shall be received from the Department.

Please number all attachments consecutively and record the number of pages attached to this application.

Number of pages attached: _____

Signature of Blood Bank Director	Date
Signature of Blood Bank Co-Director	Date
Signature of Owner	Date

Sworn before me this _____ day of _____, _____

Notary Public: _____

ONLY INITIAL APPLICATIONS NEED TO BE NOTARIZED.