APPLICATION FOR LICENSE TO OPERATE A BLOOD CENTER
Pursuant to IC 16-41-12

State Form 49621 (R / 3-00)

Indiana State Department of Health
Division of Acute Care

DIVISION OF ACUTE CARE USE ONLY
Date received
Date denied
Date approved

Forward application and all requested information to:
Indiana State Department of Health
Acute Care / Blood Center Program, Room 4A
2 N. Meridian Street
Indianapolis, IN 46204

All questions on this application must be answered completely and requested copies and / or attachments submitted. Incomplete applications will be returned without being processed.

This application and the license, which may be issued thereupon, are not transferrable between Blood Centers, Medical Directors, or Responsible Heads.

PLEASE PRINT OR TYPE

I. TYPE OF APPLICATION: (*check appropriate item*)

- ☐ Initial (*New Center*)
- ☐ Renewal of Existing License
- ☐ License Expiration Date _____
- ☐ Change of Ownership
- ☐ Anticipated Date of Sale / Transfer / Lease (*if applicable*) _____

Submit a dated and signed copy of the bill of sale, lease or other document of transfer

- ☐ Other _____

II. IDENTIFYING INFORMATION

A. Legal name of center

B. d/b/a Name of center

Address (*number and street, city, state, ZIP code*)

County	Township
Telephone number	Fax number

Include a list of all locations operated by the Blood Center. (*You may attach list*)

If Mobile Units are operated by the Blood Center, indicate the number in operation as of the date of this application

C. Type of control / ownership

- ☐ Incorporated
- ☐ Not-for-Profit
- ☐ Proprietary _____ Government
- ☐ Other

Is this facility chain affiliated? ☐ Yes ☐ No	If yes, list name

Address (*number and street, city, state, ZIP code*)

Attach a list of owners / Board of Directors / trustees identifying those individuals who are responsible for overseeing the Blood Center operations.

D. Type of operation (*check all applicable*)

- ☐ Blood Bank
- ☐ Blood Center
- ☐ Hospital
- ☐ Donor Center
- ☐ Donor Testing
- ☐ Recipients Testing
- ☐ Transfusion Service
- ☐ Blood Storage Facility
- ☐ Component Preparation
- ☐ Product Distribution
- ☐ Therapeutic Pheresis
- ☐ Therapeutic Bleeding

Is this Blood Center licensed / registered by the Federal Government? ☐ Yes ☐ No	Establishment license number	Registration number

Product license numbers: _____ _____ _____

_____ _____ _____ _____

_____ _____ _____ _____

Date of last FDA inspection	Is this Blood Center a member of a national professional / accreditation organization? ☐ Yes ☐ No

If yes, name of organization(s):

E. Personnel

Name of Medical Director	Degree(s)
Specialty	
Name of Responsible Head	Title
Qualifications	
Name of Consultant Physician	Degree(s)
Specialty	
Name of Technical Supervisor (*Laboratory Testing*)	Degree(s)
Specialty	

Technical Personnel:	**Number of Full-Time**	**Number of Part-Time**	**License / Registry (*if any*)**
Laboratory Technologist			
Laboratory Technician			
Medical Doctors			
Registered Nurses			
LPN			
Other (*specify*)			

F. Blood Components collected:

- ☐ Whole Blood
- ☐ Cryoprecipitate
- ☐ Platelets
- ☐ Recovered Plasma
- ☐ Stem Cells
- ☐ Fresh or Frozen Plasma
- ☐ Packed Red Cells
- ☐ Autologous Blood
- ☐ Directed donations
- ☐ Cord Blood
- ☐ Units for research and / or pharmaceutical products

☐ Other: (*specify*) _____

Number and type of units collected previous year: From: (*month, year*) _____/_____ To: (*month, year*) _____/_____	Number of units of whole blood drawn:
Number of units of Plasmapheresis: Single: _____ Double: _____	Number of Leukopheresis units:
Number of Plateletphersis units:	Number of Cryoprecipitate units prepared:
Other (*specify*)	

G. Donor Selection and Collection:

Attach a copy of the donor history card, Informed Consent Form, labels, record sheets, and other forms used in the blood center.

Who interviews donors? Where and what kind of training have the interviewers had?

Who collects blood from donors? Where and what kind of training have they had for blood collection?

Is a licensed physician present during donor selection and collection? ☐ Yes ☐ No	If licensed physician is not present, is one available for consultation? ☐ Yes ☐ No

When a physician is not present, who is in charge of direct supervision of donor selection and collection? (*name, title*)

H. Laboratory Testing

Attach copies of the following procedures if performed on-site. If not performed on-site, give name, address, and licensure / certification numbers of reference laboratory used.

ABO grouping and sub-grouping

Rh typing

Testing for Hepatitis viruses

HIV-I antibody and antigen testing (*screening and confirmation*)

HTLV-I testing (*screening and confirmation*)

Name of Proficiency Testing (PT) Program enrolled in?

List PT testing modules you are enrolled for

Attach copies of the last PT event testing results / scores.

Copies of the proficiency testing program results are required to be submitted to the Indiana Department of Health following receipt of each event's result (*three times annually*).

I. Test Reporting and Donor Counseling

Attach copies of procedures / policies for assuring that all reactive tests for hepatitis / HIV are repeated and those found repeatedly positive are destroyed. Include procedure, example of letters, etc. for notification of donors when confirmatory testing is inconclusive or indicates the presence of antibodies to the human immunodeficiency virus.

J. Blood Shortage Emergency

Attach a copy of blood centers written criteria for declaration of a blood shortage emergency.

K. Suppliers

Include a list of all blood centers, pharmaceutical companies, etc. which supplies blood and / or blood derivatives to or through your blood center.

Signature of Authorized Representative	Type name
Title	Date (*month, day, year*)