

ICCBBA



FACILITY REGISTRATION FORM

- REGISTRATION PROCESSING WILL TAKE APPROXIMATELY 2 4 WEEKS
- PLEASE COMPLETE EACH SECTION IN PRINT OR TYPE
- PAYMENT MUST ACCOMPANY FORM
- PLEASE FOLLOW INSTRUCTIONS REGARDING SUBMITTING COMPLETED FORM IN THE PAYMENT OPTIONS SECTION

If you need assistance with completing this form plea	E-mail: <u>gabriela.hernandez@iccbba.org</u> Fax: +1 909 793 6214
PART A:	Telephone: +1 909 793 6516
1. Facility's Full Legal Name	
2. Primary contact person to whom mailings sho	ould be sent
Last name:	First name:
Job Title:	E-mail:
3. Secondary contact person	
Last name:	First name:
Job Title:	E-mail:
4. Legal business address of firm	
Address:	
City:	State/Province:
Country:	Postal code:

5. Telephone, Fax, and Internet

Country code:	Tel:	Fax:
Web site address:		

6. Billing address

Department:		
Address:		
City:	State/Province:	
Country:	Postal code:	

7. Specify Registration type (CHECK ALL THAT APPLY) if multiple only one registration fee will apply:

will apply.				
☐ Blood	Collection	ı Facility		
Registration	Initial one-time fee \$200 includes the first Facility Identification Number Additional \$150 for each subsequent Facility Identification Number Requested (see section 8)			
Annual License Fee: Will be billed based on the total number of Donation Identification Numbers (DINs) assigned each collection or pooling event. The annual bill is calculated as follows:				
Your facility has a volume of <1,000 products (collections/pools). Annual License Fee		Annual License Fee is US\$218		
		ty has a volume between 1,001 and 23,000 s/pools) per year	Annual License Fee is US\$332	
		ty has a volume of > 23,000 products s/pools) per year	Annual License Fee will be US\$332 plus \$0.0141 for each unit over 23,000	
Please com	plete secti	on 8.1		
Blood Tra	nsfusion			
Registration	ı Fee:	Initial one-time fee \$200 includes the first Facility Ide Additional \$150 for each subsequent Facility Identified		
*Please ch	eck the ty	pe of transfusion laboratory that applies to y	our facility.	
☐ Transfu	ision Laboi	ratory (assigns ISBT 128 donation numbers)		
Annual Lice	Annual License Fee: Will be billed based on the total number of Donation Identification Numbers (DINs) assigned to each collection or pooling event. The annual bill is calculated as follows:			
	Your facilit	ty assigns <1,000 DINs per year	Annual License Fee is US\$218	
	Your facilit	ty assigns between 1,001 and 23,000 DINs per year	Annual License Fee is US\$332	
Your facility assigns > 23,000 DINs per year Annual License Fee will be US\$332 plus \$0.0141 for each unit over 23,000		plus \$0.0141 for each unit over		
Please complete section 8.1				
☐ Transfusion Laboratory (not assigning ISBT 128 donation numbers)				
Annual License Fee: \$190 (If payment of first year license fee is included with registration, check here				
Please skip to section 9				
			<u> </u>	

<u>Cellular T</u>	<u>herapy</u>			
Registration	ı Fee:	Fee: Initial one-time fee \$200 includes the first Facility Identification Number. Additional \$150 for each subsequent Facility Identification Number Requested (see section 8)		
Annual Lice	Annual License Fee: Will be billed based on the number of donations collected or processed. The annual bill is calculated as follows:			
	Your facilit	ty collects and / or process <1,000 per year	Annual License Fee is US\$227	
	Your facilit 23,000 pe	ty collects and / or process between 1,001 and r year	Annual License Fee is US\$346	
	Your facilit	ty collects and / or pools > 23,000 per year	Annual License Fee will be US\$346 plus \$0.0145 for each product over 23,000	
☐ Cellular	Therapy C	pes of cellular therapy facilities that apply to collection Facility (Please complete section 8.2) Processing Laboratory (Please complete section 8.2) Infusion Center (Please skip to section 9)		

Tissue-No	on Ocula	<u>r</u>		
☐ Tissues	s (Non Ocu	lar) Collection/Processing/Distribution Facility		
Registration	n Fee:	Initial one-time fee \$200 includes the first Facility Identification Number. Additional \$150 for each subsequent Facility Identification Number Requested (see section 8)		
Annual License Fee: Will be billed based on the number of final labeled products produced. The annual bill is calculated as follows:				
	Your facili	ty labels <1,000 final products per year	Annual License Fee is US\$218	
	Your facili per year	ty labels between 1,001 and 5,000 final products	Annual License Fee is US\$332	
	Your facili	ty labels > 5,000 final products per year	Annual License Fee will be US\$332 plus \$0.1125 for each product over 5,000	
Please com	plete secti	on 8.3		
☐ Please c	heck if you	ur facility <u>only</u> distributes tissue.		
Note: For ti		ected with intent of being processed into a cellular ility.	therapy product please mark cellular	
Tissue-O	<u>cular</u>			
☐ Tissues	s (Ocular) (Collection/Processing/Distribution Facility		
Registration Fee: Initial one-time fee \$200 includes the first Facility Identification Number. Additional \$150 for each subsequent Facility Identification Number Requested (see section 8)				
Annual License Fee: Will be billed based on the number of final labeled products produced. The annual bill is calculated as follows:			oducts produced. The annual bill is	
	Your facili	ty labels <1,000 final products per year	Annual License Fee is US\$218	
	Your facili per year	ty labels between 1,001 and 5,000 final products	Annual License Fee is US\$332	
	Your facili	ty labels > 5,000 final products per year	Annual License Fee will be US\$332 plus \$0.1125 for each product over 5,000	
Please com	plete secti	on 8.4		
☐ Please c	heck if you	ır facility <u>only</u> distributes tissue.		
Note: For ti	-	ected with intent of being processed into a cellular	therapy product please mark cellular	

HCT/P Medical Device

☐ HCT/P Medical Device Manufacturer

Registration Fee: Initial one-time fee **\$200** includes the first Facility Identification Number.

Additional \$150 for each subsequent Facility Identification Number Requested (see section 8)

Annual License Fee: Will be billed based on the number of final labeled products produced. The annual bill is

calculated as follows:

Your facility labels <1,000 HCT/P Medical Devices per year	Annual License Fee is US\$218
Your facility labels between 1,001 and 5,000 HCT/P Medical Devices per year	Annual License Fee is US\$332
Your facility labels > 5,000 HCT/P Medical Devices per year	Annual License Fee will be US\$332 plus \$0.1125 for each product over 5,000

Please complete section 8.5

Plasma Fractionator or Further Processing Facilities
*Please check the type that applies to you
☐ Plasma Fractionators who read and interpret ISBT 128 bar codes
Plasma fractionators who read and interpret ISBT 128 donation identification numbers and/or product codes, whether originating from their own collection or from a third party supplier, are required to register with ICCBBA and pay an annual license fee.
Registration Fee: none
Annual License Fee: \$5,975
Please skip to section 9
☐ Plasma Fractionators who label plasma donations with ISBT 128 bar codes
Plasma fractionators who want to use ISBT 128 donation numbers on the plasma that they collect will need to register as collection facilities and be assigned a facility identification number.
Registration Fee: Initial one-time fee \$200 includes the first Facility Identification Number.
Annual License Fee: Will be billed based on the number of units collected in the previous year. The fee is US\$0.0141 per unit, with a minimum license fee of \$332.
Please complete section 8.6
Plasma Fractionators who label derivatives with ISBT 128 or Further Processing Facilities
Plasma fractionators or Further Processing Facilities who supply product labeled with ISBT 128 are required to register with ICCBBA and pay an annual license fee.
Registration Fee: none
Annual License Fee: Will be billed based on the number of containers (units) of final ISBT 128 labeled products issued in the previous year. The fee is US\$332 plus \$0.0141 for each unit over 23,000.
For plasma derivatives other than solvent detergent plasma, the fee has not yet been determined (contact the ICCBBA office for more information).
Please complete section 8.6

Proficiency Testing			
☐ Proficiency Testing Organizations			
Registration Fee:	Initial one-time fee \$200 includes the first Facility Identification Number. Additional \$150 for each subsequent Facility Identification Number Requested (see section 8)		
Annual License Fee: \$1	190		
Please skip to section	19		

8. Activity

Provide figures on activity in your facility for your last complete fiscal year (include all sites and provide one aggregate number).

8.1

Blood Facilities	Number
Whole Blood units collected- (excludes cord blood)	
Apheresis donation procedures performed (excludes cellular therapy collections)	
Blood product pools prepared	

8.2

Cellular Therapy (e.g. apheresis, marrow, cord blood)	Number
Cellular Therapy collections	
Cellular Therapy products processed	

8.3

Tissue-Non Ocular	Number
Tissue (Non-Ocular) Final Labeled Products	
(Note: for tissues collected with intent of being processed into cellular therapy product please fill out section 7.2 Cellular Therapy collections.)	

8.4

Tissue- Ocular	Number
Tissue (Ocular) Final Labeled Products	
(Note: for tissues collected with intent of being processed into cellular therapy product please fill out section 7.2 Cellular Therapy collections.)	

8.5

HCT/P Medical Device	Number
HCT/P Medical Devices Labeled	

8.6

Plasma Fractionators or Further Processing Facilities	Number
Units collected or labeled with ISBT 128	
Products distributed that are labeled with ISBT 128	

9.	Number of Facility Ident (Complete one Part B for	ification Numbers requested: each FIN requested)				
10.	Signature of authorized I request registration of the fee (payable when invoice	person: e above named firm by ICCBBA. I understand that an annual license ed) will be required to maintain this registration.				
	Signature	Date				
		Date				
Hun	nan Development Inde	×				
	r facility is in a country with N r facility is in a country with L	MEDIUM HDI check here and reduce the fee payable by 33% OW HDI check here and reduce the fee payable by 66%				
* <u>DO</u>	ES NOT APPLY TO THE US					
Inform						
IIIIOII	nation on country HDI status	is available from the United Nations at http://hdr.undp.org/en/statistics/				
11.	Payment Options:					
	US\$ to	tal registration fee accompanying form				
	N	O PURCHASE ORDERS				
NOT	E: ADDRESS FOR RETURN	IING FORM DEPENDS UPON METHOD OF PAYMENT CHOSEN				
	Check					
Ma	ake payable to ICCBBA (in US\$	ONLY drawn on a US bank)				
		D: P.O. Box 11309, San Bernardino, CA 92423-1309				
	Credit Card (VISA or Master0					
	orount oura (VIOA or muotore	and only)				
Ca	ard number	Expiry date (MM-YY) Credit Card Security Code				
Si	gnature of authorized cardholde	Send completed form to: P.O. Box 11309, San Bernardino, CA 92423- 1309 or fax it to 909-793-6214				
	☐ Bank Draft/Wire (non-US registrants ONLY)					
Tra	ansfer appropriate amount to:	Bank of America, Commercial Banking Department 3100 Tower Boulevard, Suite 910, Durham, NC 27707 Bank Number 053000196 BIC/SWIFT: BOFAUS3N				
Pa	yable to:	ICCBBA, Account Number 000683127591				
	, 	,				
*R	•	umber here before submitting form:				

PART B:

Information from this form will be used to assign Facility Identification Numbers (FIN) and create entries in the official ICCBBA Facility Identification Number database that is maintained on the ICCBBA Website.

It is left to the discretion of the organization registering how many FINs are requested, and how they are assigned within the organization. One copy of this section must be submitted for **each** FIN requested.

Complete the following section identifying the CONTACT LOCATION for the facility. This contact location will be associated with the Facility Identification Number in the ICCBBA database and should provide the information necessary to contact the facility if any questions arise about a product bearing the particular Facility Identification Number.

Full Legal Name of Facility R	Registering		
Address line 1		Address line 2	
Address line 3		City	
State/Province, etc.	Country	Postal code	
Web Site Address			
Telephone and Fax:			
Country code Telepho	one	Fax	

Reminder: If more than one FIN is requested, duplicate this page and provide the information above for each FIN requested.

FACILITY LICENSE AGREEMENT

ICCBBA's Commitment to Registered and Licensed Facilities

ICCBBA will make available documentation of all updates and extensions to ISBT 128 to each Registered and Licensed Facility. ICCBBA maintains a Website (http://www.iccbba.org) through which updates and extensions are first published. Licensed facilities may self-select a password to gain access to the password protected area of the ICCBBA Website in order to obtain these updates and extensions. ICCBBA attempts to make certain that all data in ICCBBA databases are accurate, and will immediately make available any corrections. Data provided in the Facility Identification Number and Manufacturer Identification Code tables can only be as accurate as the most recent information provided to ICCBBA. ICCBBA will provide Help Desk support to users to promote knowledge of, and correct implementation of, the ISBT 128 Standard.

Facility's Commitment to Other Registered and Licensed Facilities

A facility that has implemented ISBT 128 will follow the standard to ensure interoperability with other facilities using the coding system.

If assistance is needed:

- The facility will work with ICCBBA to correct any nonconformities that prevent interoperability with other organizations.
- The facility will communicate to ICCBBA problems related to on-going nonconformance with the ISBT 128 Standard it encounters when receiving ISBT 128 labeled products from other facilities.

ICCBBA's Grant of License

What a Licensed Facility May Do

Use ISBT 128 and any other material to which ICCBBA owns the copyright (data identifiers, data structures, databases, access to the password protected area of the ICCBBA Website).

What a Licensed Facility May Not Do

Make copies of any item marked as "Copyright © (year[s]) ICCBBA." without express written permission, with the single exception that one copy per licensed facility may be downloaded and stored for local access (copies are always available in the password protected section of the ICCBBA Website). Share ICCBBA materials with others who are not licensed users of ISBT 128.

Warranty

ICCBBA provides no warranty that the use of ISBT 128 is suitable for any particular purpose and the selection, use, efficiency and suitability of ISBT 128 is the sole responsibility of the Licensed User.

Liability

ICCBBA's liability is limited solely to those items listed in the section "ICCBBA's Commitment to Registered and Licensed Facilities." Under no circumstances shall ICCBBA's liability exceed the current annual license fee, and ICCBBA will in no circumstances be liable for any damages whatsoever, including without limitation damages for loss of data, business or goodwill or any other consequential losses of any nature arising from the use of ISBT 128.

Termination

This License Agreement is considered to be terminated in any year in which the annual license fee as established by the ICCBBA Board of Directors has not been paid thirty (30) days after the date stipulated on the fee invoice. When this License Agreement is terminated all documentation and databases supplied to the Licensed User must be returned to the ICCBBA office at its currently published address.

Mediation/Arbitration

Any controversy arising out of this License Agreement shall be settled by non-binding mediation in the first instance and, should that prove non-satisfactory, by arbitration in the Commonwealth of Virginia, in which state ICCBBA is incorporated, in accordance with the rules of the American Arbitration Association.

Jurisdiction

Except for United States Licensed Users that are supported by state funds, any action with respect to this License Agreement must be brought in the Commonwealth of Virginia, in which state ICCBBA is incorporated. With regard to the exception noted above, Licensed Users supported by state funding may use a court within their state if such is required by the provision of state funds.